Don't Be Left Out Once Insurance Exchanges Are Active

A CHA Executive Briefing Regarding CHPSO Membership

March 1, 2011 — Web Seminar

CALIFORNIA HOSPITAL ASSOCIATION

Welcome & Program Overview

Mary Barker
California Hospital Association

Today's Agenda

- Leadership in Patient Safety

  C. Duane Dauner,
  California Hospital Association

- The PSO Law

  Ann O'Connell, JD, Nossaman, LLP

- Patient Safety Collaboratives and the Relationship to PSOs

  Art Sponseller, Hospital Council of Northern and Central California

Today's Agenda

- Navigating the PSO Law

  Ann O'Connell, JD, Nossaman, LLP

- How and Why a Hospital System Adopted CHPSO

  Barbara Pelletreau, Catholic Healthcare West

- Next Steps: CHPSO Participation

  Rory Jaffe, MD, California Hospital Patient Safety Organization

- Questions & Answers

Leadership in Patient Safety

C. Duane Dauner
California Hospital Association

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Why Patient Safety Organizations?

To Err is Human, Institute of Medicine Report, November 1999

Three major recommendations could not be implemented:

- strong legal protection for patient safety information
- shared learning from the experience of others
- strong culture of safety and communication

Congress established the PSO Law in 2005

CHA Board Responds

- Creates the California Hospital Patient Safety Organization (CHPSO)
- The only PSO by California hospitals and for California hospitals
- Mission of CHPSO:

  "Dedicated to eliminating preventable harm and improving the quality of health care delivery in California."

Affordable Care Act Provisions

- HHS program for high readmission rate hospitals includes working with a PSO (program starts Jan. 2012)
- Participation in a PSO is required of network hospitals to participate in a health care insurance exchange (Jan. 2015)

The Value of CHPSO

- Culture of safety creates provides a “safe table”—legal protections in place
- Driven by CHA members
- Works closely with the regional Patient Safety Collaboratives
- Serves as the statewide source for patient safety information
- Through alliances have access to experiences of over 700 hospitals

An Invitation to All

- More than 200 hospitals have joined CHPSO
- Thank you for taking the time to learn more

The Patient Safety Organization Law

Ann O'Connell
Nossaman, LLP

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The PSO Law

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act)

- 42 USCS § 299b-21 *et seq.*

Patient Safety and Quality Improvement Final Rule (Patient Safety Rule)

- 42 CFR Part 3
  - 73 Federal Register 70731 (November 21, 2008)

Overview

Purpose

- The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs to improve quality and safety through the collection and analysis of data on patient events.

Oversight

- US Department of Health & Human Services (HHS)
- Agency for Healthcare Research & Quality (AHRQ)

Voluntary Program

- Participation is voluntary
- But participants must comply with the PSO law

Key Elements of the Law

- Creation of PSOs
  - Requirements for certification ("listing")
  - Requirements for operating as a PSO
- Patient Safety Work Product
  - Privileges
  - Permitted Uses
  - Nonpermitted Uses
  - Penalties

In a Nutshell

- Participating providers enter into a contract with a PSO
- Providers “create” a Patient Safety Evaluation System
- Through their Patient Safety Evaluation System, providers create, collect and report Patient Safety Work Product to a PSO
- Patient Safety Work Product is privileged

What Is a Patient Safety Evaluation System? (PSES)

The –

- Collection
- Management, or
- Analysis of information

– for reporting to, or by, a PSO

Patient Safety Work Product (PSWP)

Any –

- Data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements
- (Or copies of any of these)

– which…

Patient Safety Work Product

Which

- Could improve patient safety, health care quality, or health care outcomes **and**
- Are assembled or developed by a Provider for reporting to a PSO … **and** which **are reported to a PSO**; **or**
- Identify or constitute the **deliberations or analysis of,** or identify the fact of reporting pursuant to, **a PSES**

What Is Not PSWP?

- Patient medical records
- Billing and discharge information
- Other original patient or provider information
- Information collected, maintained or developed separately, or exists separately from a PSES

PSWP Is Confidential

- May not be "disclosed"
- Disclosure – means to outside entities
- Exceptions
  - Criminal proceedings (in limited circumstances)
  - Equitable relief for reporters
  - **Authorizations**
  - **Patient safety activities**
  - Nonidentifiable PSWP
  - FDA
  - **Voluntary disclosure to accrediting body**
  - **Business operations**
  - Law enforcement (limited circumstances)

PSWP Is Privileged

- May not be subpoenaed
- Not subject to discovery
- Not subject to disclosure (e.g., under FOIA)
- May not be admitted into evidence in any
  - Court proceeding
  - Administrative agency proceeding
  - **Professional disciplinary proceeding** of a body established or specifically authorized under State law

No Retaliation Against Reporters

- May not take any adverse employment action against individuals who report to a PSES or a PSO
  - Loss of employment, failure to promote, failure to provide employment-related benefit
  - Adverse evaluation or decision relating to accreditation, certification, credentialing or licensing of an individual

Enforcement & Penalties

- Civil $ penalties for knowing or reckless disclosure of PSWP in violation of the confidentiality provisions
  - ↑$10,000 per violation
  - Same procedures as for CMP under SSA §1128A
  - Penalties not imposed under both HIPAA and PSA for a single act or omission

Patient Safety Collaboratives and the Relationship to PSOs

Art Sponseller
Hospital Council of Northern and Central California

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Patient Safety Collaboratives

Regional Patient Safety Collaboratives:

- Current Efforts
  - Patient Safety First, A California Partnership for Health
  - Beacon Bay Area
  - CHPSO
    - Just Culture
    - Safe Table in San Mateo
    - Safe Tables at Collaborative meetings

CHPSO and the Collaboratives

CHPSO and the Collaboratives

- Rationale for local collaboratives
- CHPSO indentifies areas of need and shares best practices
- Collaboratives “spread” solutions and help to hard wire change down to the unit level

Navigating the PSO Law

Ann O'Connell
Nossaman, LLP

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Navigating the PSO Law

- Creating your PSES
- Adoption of Policies & Procedures describing:
  - What and how information will be entered into the PSES to → PSWP
  - How PSWP will be used
  - Who can access/manage the PSWP
  - How reporting will be accomplished
  - How to handle some of the key "interfaces"

→ CHPSO has created a Sample Policy that may be adapted by CHPSO-participating hospitals

Key "Interfaces"

- Use of PSWP – very few limitations **within** the hospital
  - Patient Safety Activities
  - Other internal uses (so long as not prohibited use – see below)
  - Business Operations – May disclose to
    - contractors assisting with patient safety activities
    - attorneys, accountants, other professionals for any purpose (but their use is subject to the confidentiality and permitted use restrictions)
  - May not otherwise disclose the PSWP **outside** the hospital
    - Unless per an exception
  - May not use PSWP for **prohibited uses**, e.g.,
    - Mandatory reporting
    - Peer review hearing
    - Evidence in litigation

Key "Tools" for Managing These Interfaces

- Your policy itself – how you design it to do as many things as possible (automatically) via the terms of the policy
- "Lingering" → ability to house PSWP within your PSES for an indefinite period prior to reporting
- De-designation → ability to move (some) unreported PSWP out of the PSES
- Copies → ability to bifurcate information:
  - One set of information developed and managed as PSWP
  - Another set of information developed and managed as non-PSWP

Basics

Protected PSWP is created by this formula:

~ PSWP

+ PSES

= Privileged PSWP

And,within limits, can be managed by this formula:

Privileged PSWP

- PSES

≠ PSWP

Basic Steps

- Enter info meeting threshold definition of PSWP into your PSES
- If needed for other purposes:
  - De-designate “original”
    - Use for other purposes
  - Make a copy of “original”
    - Re-enter copy → PSWP
- Re-entered PSWP (and its progeny – deliberations or analyses within the PSES) are protected
- Report PSWP to PSO

More “Tools”

- Provisions that facilitate needed uses of information:
  - Definition of “disclosure”
    - Use within the hospital is not a disclosure
- Exceptions, e.g.:
  - Business operations
  - Voluntary disclosure to accrediting body
  - Authorization
  - De-identification (removing direct identifiers)
  - Non-identifiable information (removing direct and indirect identifiers)

How to's…

- Mandatory reporting
- Government inspections
- Joint Commission (or other accrediting body access)
- Peer review
- Personnel actions
- Litigation

Mandatory Reporting

- Make report using original source information
  - Never event report requirements are very general
  - Also, if you need to access information already in your PSES
    - No prohibition on using the PSWP to identify key information
    - Can always return to original source of that information
    - Can de-designate not-yet-reported information
    - Can disclose information that does not identify providers
    - And hospital can authorize disclosure (of its identifiable information)

Government Inspections

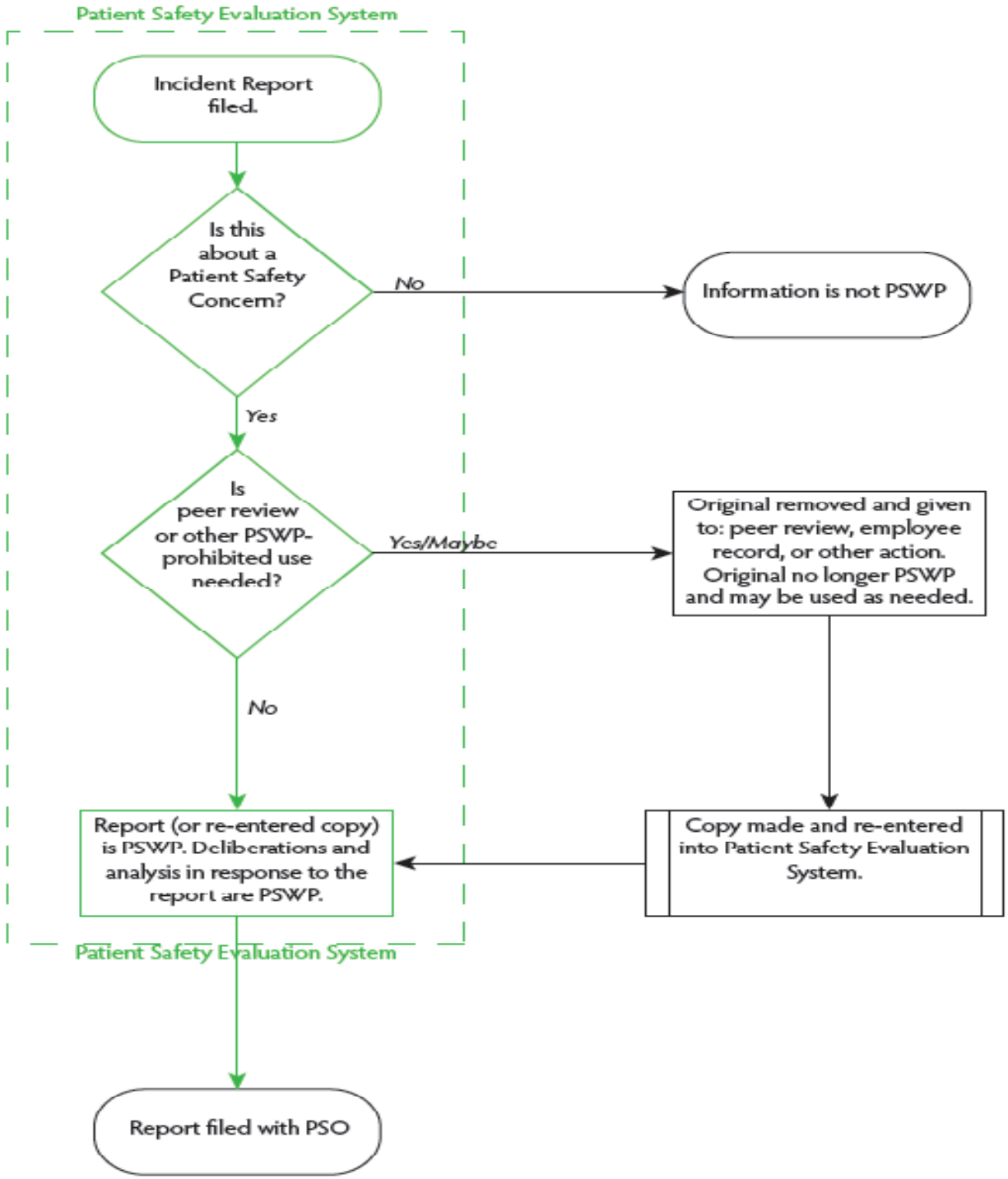
- Hospital has options
  - Not disclose PSWP/assert the privilege
  - Or use the tools described above (use original information, de-designate, disclose non-identifiable information, authorize identifiable information) to provide information to regulators as hospital deems necessary/useful to responding to inquiries

The Joint Commission (or other accrediting body access)

- Same tools as for governmental inspections
- Plus, special provisions re Root Cause Analyses:
  - Assumption (in the sample policy) is that most RCAs will be conducted within your PSES, and thus be PSWP
    - RCAs conducted outside the PSES are not encumbered
  - RCAs that are PSWP may be disclosed to accrediting body if:
    - All identified individuals agree; or
    - All individual identifiers have been removed

Medical Staff Peer Review

- Sample Policy assumes all peer review is conducted outside of the PSES
- Early triaging of events that would be reported to a Medical Staff (MS) Committee for review
  - De-designate and use for peer review
  - May copy and return copy to PSES
  - Conduct (non-MS peer review) PSA within the PSES
  - Report copy to the PSO as PSWP
- If later discover need to use PSWP that has not been de-designated (and cannot be, because it's already been reported or cannot get authorizations or sufficiently de-identify), then would need to go back to original records and re-create outside of the PSES


Patient Safety Evaluation System
Incident Report filed.
Is this about a Patient Safety Concern?
No
Information is not PSWP
Yes
Is peer review or other PSWP-prohibited use needed?
Yes/Maybe
Original removed and given to: peer review, employee record, or other action. Original no longer PSWP and may be used as needed.
No
Report (or re-entered copy) is PSWP. Deliberations and analysis in response to the report are PSWP.
Copy made and re-entered into Patient Safety Evaluation System.
Patient Safety Evaluation System
Report filed with PSO

Hospital Personnel Actions

- Not encumbered by the peer review prohibition, but because of potential for litigation, handle in essentially the same manner
- Early triaging of events that may require personnel action
  - De-designate and use for personnel actions
  - May copy and return copy to PSES
  - Conduct PSA within the PSES
  - Report copy to the PSO as PSWP
- If later discover need to use PSWP that has not been de-designated (and cannot be, because it's already been reported or cannot get authorizations or sufficiently de-identify), then would need to go back to original records and re-create outside of the PSES

Litigation

- Ability to disclose to attorney under "business operations" exception, without loss of PSWP privilege
  - But cannot use as evidence under that exception
- Generally do not use QA information in litigation
- But, if need PSWP for evidence, same general approach
  - Early triage
  - De-designate information that may need to be used in litigation
  - May need to go back to original sources if already reported or cannot de-designate
  - Or use authorizations or de-identification

In the Final Analysis

- Law offers more protections than are available if not participating in PSO
- Other protections are not affected – i.e., 1157, other immunities remain intact
- Not perfect
- Does require careful management – but it is manageable

Patient Safety Organization – CHW's Adoption of CHPSO

Barbara Pelletreau, RN, MPH

Vice President, Patient Safety & Clinical Risk Management

CALIFORNIA HOSPITAL ASSOCIATION

Migrating towards a Patient Safety Organization

- Encouraged extensive reporting & analysis of events and near misses
  - Electronic is best, paper is second best
- Committed to safe care, transparency and outcomes
- Ultimately, patient centered care at all levels

Definition of an "EVENT"

….any situation or set of circumstances that results in an adverse outcome to a patient or could have

Why a PSO for CHW?

- Commitment from Senior leadership for safest care
- Continue to support the hospitals' endeavors to "dive deep" on their safety opportunities (RCAs, analysis, presentation of findings, sharing of stories)
- Achieve maximum protection from regulations to protect our "safety work" and those involved
- Assistance from CHPSO and legal partners

Where are we now?

- Finalizing Policy & Procedure to distribute and adopt
- Hospitals are adding “Patient Safety Work Product” to RCAs and other analysis
- Aligning with claims management to comply with regulations
- Re-educate leadership with a focus on risk managers/patient safety officers

Next Steps: CHPSO Participation

Rory Jaffe, MD
California Hospital Patient Safety Organization

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CHPSO Focuses on "To Err is Human" Recommendations

- Provides a safe environment (legally protected) for addressing and sharing event information
- Facilitates mutual learning from shared experiences
- Encourages widespread development of a safety culture

Participation Requires

- Leadership commitment
- Signed contract
- Willingness to share (in a protected environment) patient safety events and responses
- Eventual transmission of copies of incident reports (volume determined by participant)
- No new data needs to be collected
- Not a “reporting initiative”—rather, a “sharing and learning initiative”

Support

- Policy template developed from extensive analysis and reconciliation of the new legal privilege with typical hospital processes
- Free technical support for development of electronic transmission from incident reporting system
- Specific support for patient safety issues upon request

CHPSO's Mission

- Dedicated to eliminating preventable harm and improving the quality of health care delivery in California hospitals

Join the Journey

- Contract: www.chpso.org/signup.asp
  - No cost, cancellable without cause
  - Amount of participation determined by each organization

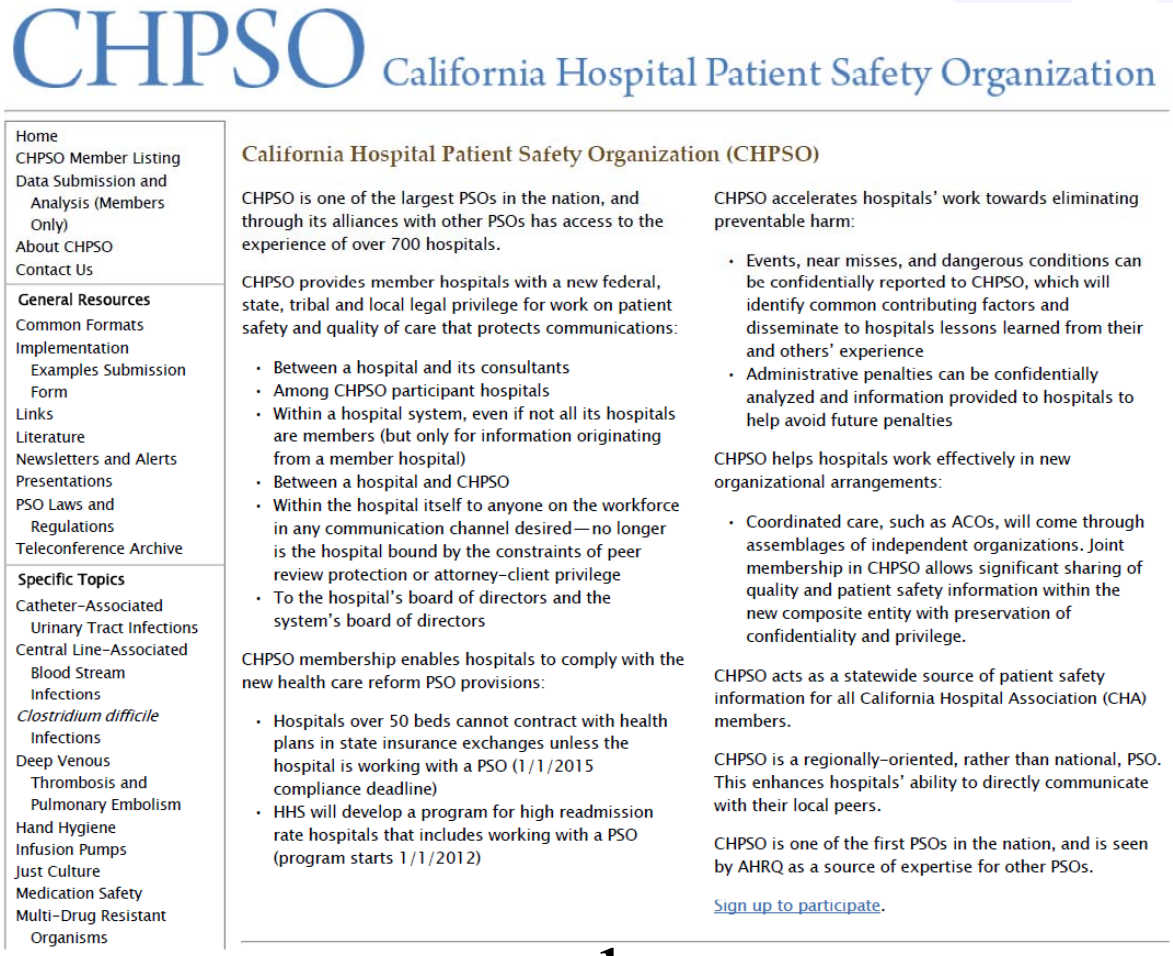
- Contact Rory Jaffe, MD:
  (916) 552-7568
  rjaffe@calhospital.org

Questions

Online questions:
Type your question in the Q & A box, hit enter

Phone questions:
To ask a question hit *1
To remove a question hit *2

CHPSO Website



CHPSO California Hospital Patient Safety Organization

Home
CHPSO Member Listing
Data Submission and Analysis (Members Only)
About CHPSO
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General Resources
Common Formats
Implementation Examples Submission Form
Links
Literature
Newsletters and Alerts
Presentations
PSO Laws and Regulations
Teleconference Archive

Specific Topics
Catheter-Associated Urinary Tract Infections
Central Line-Associated Blood Stream Infections
Clostridium difficile Infections
Deep Venous Thrombosis and Pulmonary Embolism
Hand Hygiene
Infusion Pumps
Just Culture
Medication Safety
Multi-Drug Resistant Organisms

California Hospital Patient Safety Organization (CHPSO)

CHPSO is one of the largest PSOs in the nation, and through its alliances with other PSOs has access to the experience of over 700 hospitals.

CHPSO provides member hospitals with a new federal, state, tribal and local legal privilege for work on patient safety and quality of care that protects communications:

- Between a hospital and its consultants
- Among CHPSO participant hospitals
- Within a hospital system, even if not all its hospitals are members (but only for information originating from a member hospital)
- Between a hospital and CHPSO
- Within the hospital itself to anyone on the workforce in any communication channel desired—no longer is the hospital bound by the constraints of peer review protection or attorney-client privilege
- To the hospital's board of directors and the system's board of directors

CHPSO membership enables hospitals to comply with the new health care reform PSO provisions:

- Hospitals over 50 beds cannot contract with health plans in state insurance exchanges unless the hospital is working with a PSO (1/1/2015 compliance deadline)
- HHS will develop a program for high readmission rate hospitals that includes working with a PSO (program starts 1/1/2012)

CHPSO accelerates hospitals' work towards eliminating preventable harm:

- Events, near misses, and dangerous conditions can be confidentially reported to CHPSO, which will identify common contributing factors and disseminate to hospitals lessons learned from their and others' experience
- Administrative penalties can be confidentially analyzed and information provided to hospitals to help avoid future penalties

CHPSO helps hospitals work effectively in new organizational arrangements:

- Coordinated care, such as ACOs, will come through assemblages of independent organizations. Joint membership in CHPSO allows significant sharing of quality and patient safety information within the new composite entity with preservation of confidentiality and privilege.

CHPSO acts as a statewide source of patient safety information for all California Hospital Association (CHA) members.

CHPSO is a regionally-oriented, rather than national, PSO. This enhances hospitals' ability to directly communicate with their local peers.

CHPSO is one of the first PSOs in the nation, and is seen by AHRQ as a source of expertise for other PSOs.

Sign up to participate.

www.chpso.org

Upcoming CHA Programs

2011 Rural Health Care Symposium
March 16 – 18, 2011; San Diego

Accountable Care Organization Web Seminar
March 23, 2011; 10:00 a.m. – Noon (assuming rule is released)

Office of Federal Contract Compliance Programs Web Seminar
March 24, 2011; 10:00 a.m. – Noon

Go to www.calhospital.org/education for more information.

Upcoming CHA Programs

Health Policy Legislative Day
April 5 & 6, 2011; Sacramento

California Congressional Action Program
April 10 – 13, 2011; Washington, D.C.

Post-Acute Care and Health Care Reform—Preparing for Change
April 28, 2011, Walnut Creek

Consent Law Seminar
May 5, San Ramon; May 24, Ontario; May 25, San Diego
June 1, Sacramento; June 7, Glendale; June 8, Costa Mesa

Go to www.calhospital.org/education for more information.

Evaluation

Thank you for participating in today's seminar. An online evaluation will be sent to you shortly.

For education questions, contact Mary Barker at (916) 552-7514 or mbarker@calhospital.org.

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