Katten

Patient Safety Work Product (PSWP) Privilege in the Context of Patient Safety Organizations

December 19-20, 2019

1:00 pm - 2:00 pm

Michael R. Callahan, Of Counsel
Katten Muchin Rosenman LLP
312-902-5634 (phone)
michael.callahan@katten.com

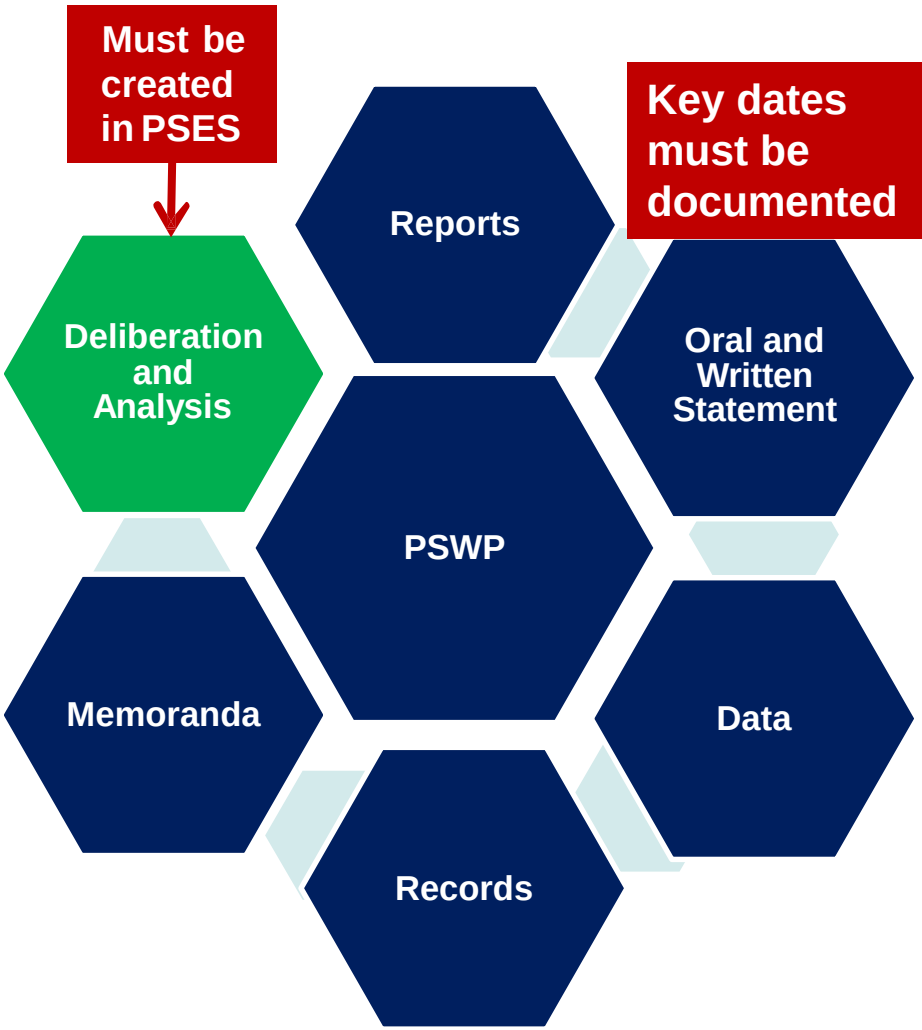
Patient Safety and Quality Improvement Act of 2005

- Privileged Patient Safety Work Product
  - Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;
- And that:
  - Are assembled or developed by a provider for reporting to a PSO and are reported to a Patient Safety Organization (PSO), which includes information that is documented as within a patient safety evaluation system (PSES) for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
  - Are developed by a PSO for the conduct of patient safety activities; or
  - Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

Patient Safety Act

- What types of information can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality?
  - Medical error or proactive risk assessments, root cause analysis
  - Risk Management — Not all activities will qualify such as claims management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
  - Outcome/Quality—may be practitioner specific
  - Peer review
  - Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks
  - Deliberations or analysis

What is Patient Safety Work Product (PSWP)?



Requirements

Data which could improve patient safety, health care quality, or health care outcomes

- Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO

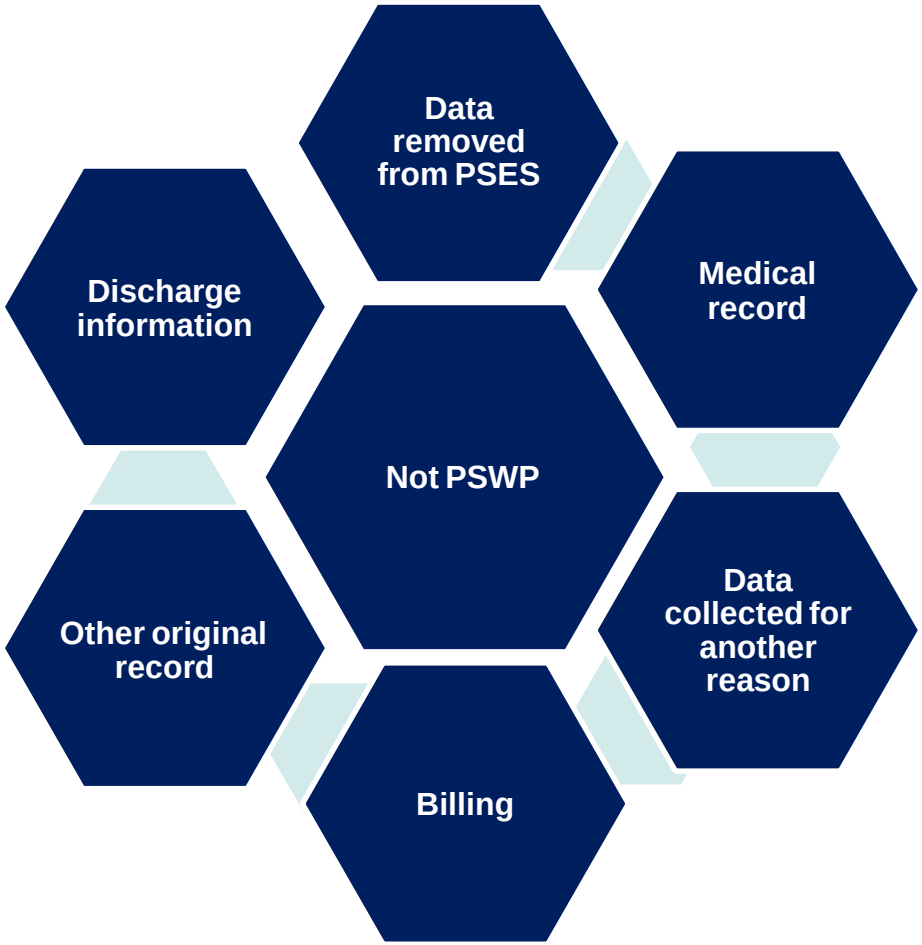
Analysis and deliberations conducted within a PSES

- Data developed by a PSO to conduct of patient safety activities

Patient Safety Act

- What is not PSWP?
  - Patient's medical record, billing and discharge information, or any other original patient or provider information
  - Information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP
  - PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES is no longer considered PSWP if:
    - Information has not yet been reported to a PSO; and
    - Provider documents the act and date of removal of such information from the PSES

What is Not PSWP?



Requirements

Information collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.

- **Data removed from a patient safety evaluation system**

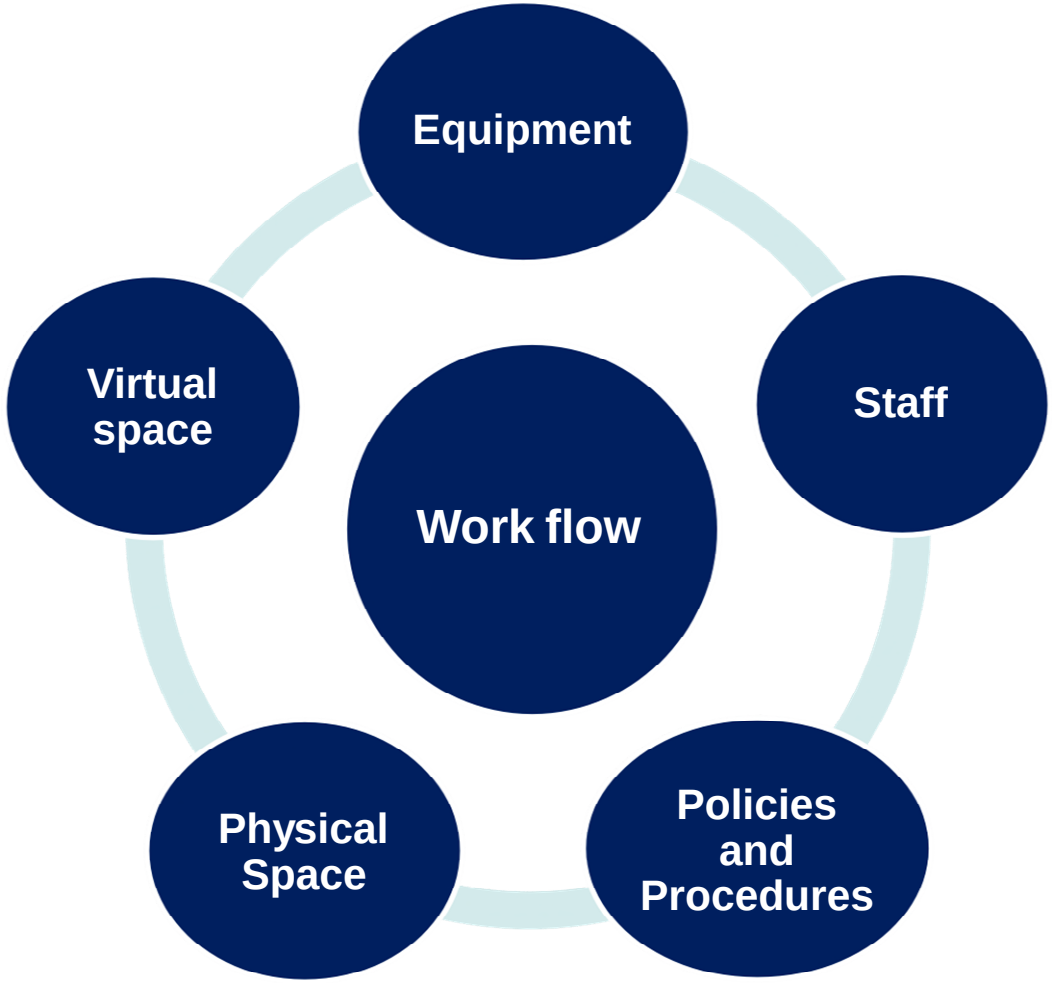
Data collected for another reason

Patient Safety Act

- — Reports that are the subject of mandatory state or federal reporting or which may be collected and maintained pursuant to state or federal laws be treated as PSWP
  - California has mandatory adverse patient event reporting requirements (California Department of Public Health, Health and Safety Code Section 1.279.1(d)(1)-(7)).
- What entities are covered under the Act?
  - — All entities or individuals licensed under state law to provide health care services or which the state otherwise permits to provide such services, i.e., hospitals, SNFs, physicians, physician groups, labs, pharmacies, home health agencies, etc.
  - — A non-licensed corporate entity that owns, controls, manages or has veto authority over a licensed provider is considered a provider.

Patient Safety Evaluation System (PSES)

The collection, management, or analysis of information for reporting to or by a PSO. A provider's PSES is an important determinant of what can, and cannot, become patient safety work product.

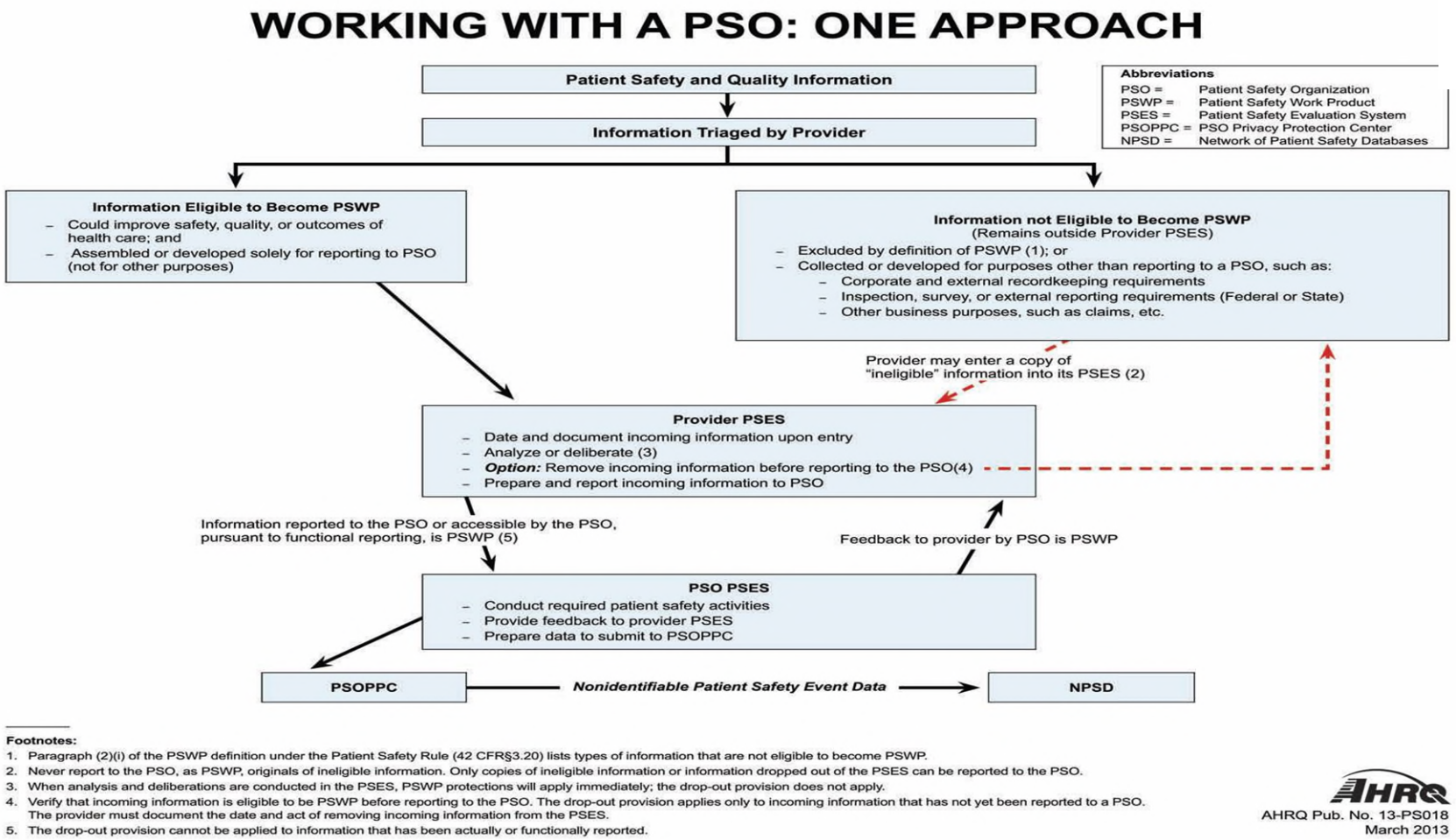


PSES Operations

Establish and Implement a PSES to:

- Collect data to improve patient safety, healthcare quality and
- healthcare outcomes
- Review data and takes action when needed to mitigate harm or improve care
- Analyze data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conduct Proactive Risk Assessments, in-depth reviews, and aggregate medication errors
- Determine which data will/will not be reported to the PSO
- Report to PSO
- Conduct auditing procedures

PSO Participation Schematic



PSWP is Privileged:

Not Subject to:

- subpoenas or court order
- discovery
- FOIA or other similar law
- requests from accrediting bodies or CMS

Not Admissible in:

- any state, federal or other legal proceeding
- state licensure proceedings
- hospital peer review disciplinary proceedings

Patient Safety Act Privilege and Confidentiality Prevail Over State Law Protections

The privileged and confidentiality protections and restriction of disciplinary activity supports development of a Just Learning Culture

State Peer Review

- Limited in scope of covered activities and in scope of covered entities
- State law protections do not apply in federal claims
- State laws usually do not protect information when shared outside the institution – considered waived

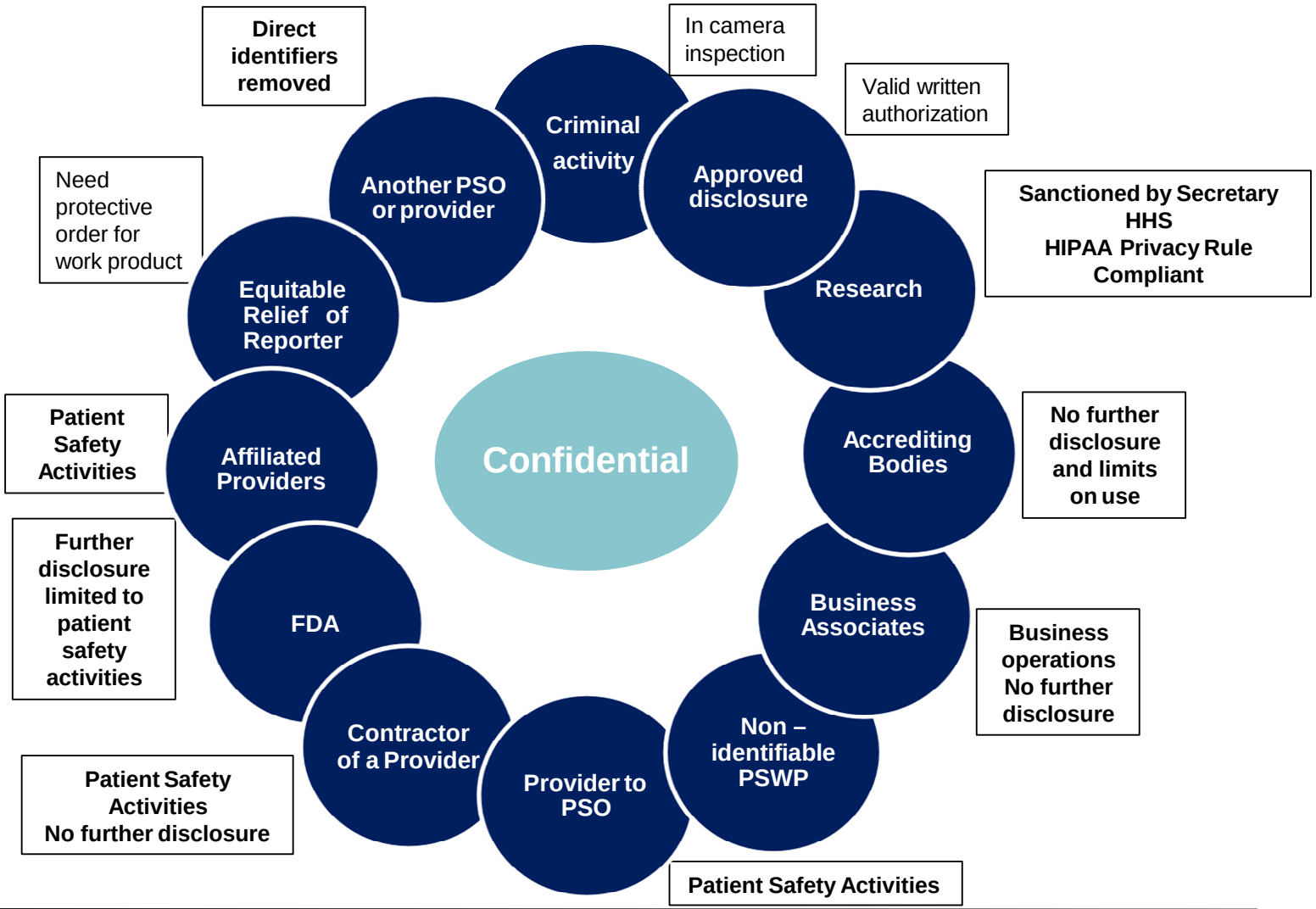
Patient Safety Act

- Consistent national standard
- Applies in all state and federal proceedings
- Scope of covered activities and providers is broader
- Protections can never be waived
- PSWP can be more freely shared throughout a health care system
- PSES can include non-provider corporate parent

Working with a PSO must be implemented in a way that facilitates a Just Learning Environment while taking advantage of privilege and confidentiality protections.

PSWP is confidential and not subject to disclosure with limited exceptions

Please see Patient Safety Final Rule



University of California PSES

What Comprises the University's Patient Safety Evaluation System (PSES)?

- The PSES includes the collection, management and/or analysis of Patient Safety Concern information recorded in the University Event Reporting System (ERS) for reporting to a PSO. **It includes information documented in the ERS and also deliberation and analysis of a Patient Safety Concern.**
  - A Patient Safety Concern includes:
    - A patient safety event that reached the patient, whether or not there was harm;
    - A near miss or close call - a patient safety event that did not reach the patient; or
    - An unsafe condition - circumstances that increase the probability of a patient safety event.

University of California PSES

— It may also include all activities, communications and information reported or developed by individuals or committees, such as data analyses, Root Cause Analyses, outcome reports and minutes, for the purpose of improving patient safety and/or healthcare quality

Creation of PSWP

- PSWP is created automatically upon filing an event report in the ERS that involves a Patient Safety Concern. All Patient Safety Concern information is collected and/or developed with the intent to report to the PSO.
- If so designated by Authorized Staff, PSWP may encompass the data collection efforts leading up to making the Event report. The date of entry into the PSWP is the date these activities occur.

University of California PSES

- **PSWP is created when deliberations and analysis (D or A) related to a Patient Safety Concern is conducted**. The date of entry into the PSES is the date these activities occur. **PSWP protections will apply immediately. Deliberations and analysis cannot be de-designated as PSWP. Documents included in this category include but are not limited to**:
  - Failure Mode Effects Analysis (FMEA)
  - Root Cause Analysis (RCA) not otherwise reported in the ERS
  - Data analysis reports & comparative outcomes
  - Patient Safety Committee minutes
  - Quality Improvement Committee minutes

University of California PSES

- Patient Safety Activities
  - Patient Safety Activities may be conducted by any individual, committee or body that has assigned responsibility for any such activities. The workforce includes faculty, staff, trainees, volunteers, and contractors who perform work under the direct control of the University. Committees include but are not limited to:
    - Patient Safety Committees
    - Clinical Performance Improvement Committees
    - Risk Management Committees
    - UC Chief Medical Officers/Chief Nursing Officers
    - UCOP Risk Services and/or Committees
    - Audits and Compliances Committee
    - Quality Improvement Committees
    - Medication Safety Committees
    - The Regents Health Services Committee
    - Center for Healthcare Quality Innovation
    - UCOP Data Management System
    - Other Regents committees with jurisdiction

University of California PSES

- An RCA conducted by a medical staff peer review committee is not PSWP unless specifically designated as such.
- Medical staff or medical peer review activities are not conducted within the PSES. Information copied from these activities may be incorporated into the PSES and designated as PSWP for use in non-medical staff peer review activities, as described in Section III.B.1.a.1, above.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **Background**
  - Case involves a lawsuit brought by the estate of a patient alleging that Ingalls Memorial Hospital and its employees committed malpractice when it failed to adequately monitor the patient's blood glucose levels.
  - The lawsuit further alleged that the patient's subsequent injuries caused by this negligence contributed to her death.
  - During the course of discovery the hospital objected to interrogatories which sought a number of incident reports and complaints arguing that the information was privileged from discovery under both the Illinois Medical Studies Act and the Patient Safety and Quality Improvement Act of 2005 ("PSA").
  - The plaintiff also requested that the hospital produce documents which described any statements made by the decedent, a family member or anyone with knowledge regarding issues addressed in the lawsuit.
  - Upon refusal to produce the documents, the plaintiff filed a motion to compel.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- Ultimately, only three documents remained in dispute which included two incident reports involving the patient's care and the complaint made by the patient's daughter to a hospital employee regarding the patient's treatment.
- All three documents, which were electronically reported to the hospital's PSO, contained the heading "Healthcare Safety Zone Portal" in addition to the name "Clarity Group Inc. Copyright" at the bottom of each page.
- Each document also included the date on which the documents were created and reported to the PSO.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **Hospital's Response to Motion to Compel**
  - In support of its response to the motion to compel, the hospital submitted two affidavits from its associate general counsel which contained the following representations:
    - The hospital contracted with Clarity PSO in 2009 to improve the hospital's patient safety and quality of care.
    - The documents in dispute were created, prepared and generated for submission to the PSO.
    - The Healthcare Safety Zone Portal provided the means by which the hospital reported this information to Clarity and were prepared "solely" for submission to Clarity.
    - The documents were not part of the patient's original medical records which had already been produced to the plaintiff.
    - The documents had never been removed from the hospital's PSES for any purpose other than for internal quality purposes.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **Hospital's Response**
  - The documents have not been reported to or investigated by any agency or organization other than Clarity.
  - There were no other reports pertaining to the incidents alleged in the plaintiff's complaint that were collected or maintained separately from the hospital's PSES.
  - Interestingly and importantly, the plaintiff never filed a response nor did the attorney object or attempt to rebut information contained in the affidavits.
- **Trial Court's Decisions**
  - The trial court ordered and the hospital agreed to submit the disputed documents for an in camera inspection.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- Upon review of the documents, the court determined that some of the information in the incident reports sent to the PSO should have been included in the patient's medical records and therefore ordered the hospital to turn over to the plaintiff those portions of the incident reports.
- The hospital refused and was therefore held in "friendly contempt" which allowed for an automatic appeal to the Appellate Court.

- **Appellate Court's Decision**
  - The Appellate Court began its analysis of the PSA by citing to the 1999 report from the Institute of Medicine entitled "to Err is Human: Building a Safer Health System" which served as the primary basis for the passage of the Act.
  - The PSA identified that the privilege protections that are incorporated into the law are "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events".

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- In determining whether the documents in dispute were privileged Patient Safety Work Product ("PSWP") the Court recognized that there are three distinct ways of creating privileged documents, the "reporting pathway", which includes actual "functional reporting", as well as treating information as "deliberations or analysis".
- Because the hospital argued that the documents were PSWP through the reporting pathway the court examined whether the hospital met all of their requirements under the PSA and further whether any exceptions applied that would prohibit the information from being privileged.
- In determining that the documents did qualify as PSWP, the court made the following findings:
  - The court documents demonstrate "that they are an amalgamation of data, reports, discussions, and reflections, the very type of information that is by definition patient safety or product".

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- The affidavits established that the documents were assembled and prepared by Ingalls “solely” for submission to Clarity PSO and were reported to the PSO.
- The information contained in the documents had the ability to improve patient safety and the quality of healthcare.
- The documents themselves bear the dates information was entered into the patient safety evaluation system as represented in the unrebutted affidavits.
- The Court then responded to the plaintiff’s arguments that the documents were not PSWP because one or more exceptions under the Act applied.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **The information was required to be in the patient's medical record and therefore was not privilege**
  - Under the PSA, "original records" such as a patient's medical record, billing and other related information are not privileged.
  - The trial court ruled that factual information which was included in the reported incident reports contained information which should have been included in the patient's medical record.
  - The plaintiff also argued that there was a significant lack of information in the medical record which had been produced to the plaintiff as well as significant gaps of time during which other information should have been included in the medical record. The hospital, therefore, was trying to hide information under the "guise of patient safety work product".

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- The Court recognized the Illinois Hospital Licensing Act requires that a medical record meet certain documentation requirements and that the PSA "does not permit providers to use privilege and confidentiality protections… to shield records required by external record keeping or reporting, and if the hospital in fact failed to meet these requirements there are "associated consequences for such failure".
- This failure, even if it occurred, does not mean that the information loses its privileged status simply because a report may include facts or other information that might also be found in the medical records.
- The Court further noted that the documents in question were created weeks after the patient was treated at the hospital and therefore "nothing in the records lead us to believe that the documents were [patient's] original medical records or contained information that should have been included in the original medical records."

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- The Court also pointed out that discovery had not yet been completed and that the Plaintiff was entitled to depose individuals regarding any facts surrounding the patient's treatment.

- **The documents were not collected solely for the purpose of reporting to a PSO.**
  - Under the PSA, documents, reports, analyses, and other information that is collected for a purpose other than reporting to a PSO or which is collected outside of a provider's PSES is not privileged.
  - The affidavit submitted by the hospital indicated that the documents in question were in fact prepared "solely" for submission to the PSO.
  - Because this representation was unrebutted by the Plaintiff the court was obligated to accept the hospital's representation.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- Note: There is nothing under the PSA which makes reference to the word “solely”. This so called standard, which is reflected in the HHS PSO Guidance, and on which plaintiffs and courts have sometimes relied, does not mean that the information collected within the PSES and reported to the PSO or treated as deliberations or analysis cannot be used for other internal purposes. In fact, it is expected that PSWP is used by the hospital to improve patient safety and reduce risk.
- If, however, the information in question was required to satisfy an external obligation or was used for a purpose which is separate from improving patient care or reducing risk and is not identified within the PSES, a provider cannot make an after the fact argument that the information is now privileged and not subject to discovery.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **Information was collected to satisfy a reporting requirement and therefore did not qualify as PSWP.**
  - The PSA clearly states that if a report that the hospital claimed as privileged was required to be made to a state or federal government or agency, the hospital cannot try to hide that information within its PSES and claim it was privileged.
  - In this case, the plaintiff cited to the Illinois Adverse Healthcare Events Reporting Law of 2005 which requires the reporting of certain identified adverse events to the Illinois Department of Public Health.
  - The Plaintiff also cited to the Florida Supreme Court's in Charles v. Southern Baptist Hospital as well as other state court decisions to further support its argument that the disputed documents were not privileged.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- In response, the Court pointed out that the Act in question had never been implemented in Illinois and therefore was not applicable.
- The plaintiff did not cite to any other statute requiring that the disputed documents had to be reported or had to be collected and maintained and made available to a state or federal agency. Therefore, this argument by the plaintiff was rejected.

- **Allowing the documents to remain privileged will permit healthcare providers to hide valuable information and thus impede the truth seeking process.**
  - This is an argument that was made by both the plaintiff and an amicus brief submitted by the Illinois Trial Lawyers Association. In response to this argument the Court provided the following analysis:
    - "However, nothing about these documents being privileged renders the facts that underline the [PSWP] as also privileged."

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- "Plaintiffs can still obtain medical records, as plaintiff did in this case, have their experts analyze and make opinions about those records, and depose doctors and nurses regarding an incident."
- "When there is no indication that a healthcare provider has failed to comply with its external record-keeping and reporting requirements and it creates supplementary information for purposes of working with a Patient Safety Organization to improve patient safety and the quality of healthcare, that provider is furthering the Patient Safety Act's objectives while not preventing the discovery of information normally available to a medical malpractice plaintiff. Under these circumstances, that additional information must be protected from disclosure."

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **Preemption Analysis**
  - Under the PSA, the federal privilege protections preempt any state or other law which would otherwise require that the information be subject to discovery and admissible into evidence.
  - This preemption standard was ignored by the Florida Supreme Court in the Charles decision in which it determined a state constitutional amendment, which gives patients broad access to any and all information relating to a hospital or physicians qualifications or past adverse events, preempted the PSA rather than the other way around.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- This decision has been roundly criticized and in fact, HHS has stated in a pending federal case that the PSA preempts all laws including Amendment 7, the Florida constitutional amendment cited by the Florida Supreme Court.
- The Appellate Court agreed with the preemption standard in the PSA and stated as follows:
  - "In other words, when information is patient safety work product, the Patient Safety Act should be construed as preempting any state action requiring a provider to disclose such work product… [c]onsequently, the Patient Safety Act preempts the circuit court's production order"

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- **Background**
  - This is a medical malpractice case arising from a claim that the defendants failed to test or treat him for a MRSA infection which because worse subsequent to an elective procedure.
  - The case was in federal court based on diversity jurisdiction.
  - Plaintiff sought to discover information regarding Guthrie's infection-prevention procedures.
  - Defendant Clinic asserted privilege protections under the:
    - PSQIA
    - Pennsylvania Medical Care Availability and Reduction of Error Act ("MCARE")
    - Pennsylvania Peer Review Protection Act

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- **Disputed Documents and Decision**
  - "A copy of all infection prevention and infection control materials which Defendants' received prior to May 1, 2017 from Vizient PSO and/or any other company"
    - MCARE does not apply to Vizient materials because it only protects documents "solely prepared or created for the purpose of complying with [state law] or of reporting…"
    - MCARE only applies to providers. Vizient is and therefore MCARE did not provide any protection to prevent discovery.
    - The court, however, found that the PSQIA applies to documents produced by a PSO for the purpose of conducting patient safety activities and therefore the Vizient materials were privileged under the Act.

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

— "A copy of any and all correspondence and communications between defendant and any federal, state, county or local governmental agency within the past 5 years on the subject of infection prevention, infection reporting, infection management and infection rates"

- Government correspondence is not part of Guthrie's PSES was bit dusckised to Vizient PSO.
- Consequently, these communications are not privileged under PSQIA or any other statute.

— A copy of Defendant's agenda, notes and any and all written records of Defendant's monthly (or other than monthly) quality committee meetings…insofar as they discuss infection prevention or infection control"

- "The is the quintessential example of patient safety work product"
- "Quality committee meetings are a core aspect of Guthrie's [PSES]"

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- ""Agendas, notes and other written records from these meetings are squarely work product and are 'deliberations or analyses' of a [PSES]"
  - All of these materials are privileged under the PSQIA, MCARE and the Pennsylvania Peer Review Protection Act
- Deposition of Clinic witness about quality committee meetings, knowledge gained through the PSES, how the committee meetings determine infection preparedness, the data used to reach preparedness conclusions and why they collected certain data and not others.
  - This information was privileged because the questions sought information generated within the PSES
  - Policies are not privileged

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- **Impact and Takeaways**
  - — Stresses the importance of a provider's PSES policy and detailed identification of patient safety activities and what is considered and treated as PSWP
  - — Multiple privilege statutes can apply – they are not mutually exclusive
    - First reported case to rely on "deliberations and analyses" standard for creating PSWP
    - Policies are not protected
    - Communications with government officials are not protected
    - Does not rely on the "sole purpose" standard which is a requirement under MCARE although the court did reference that documents were prepared "for reporting to a PSO"

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

- **Background**
  - Plaintiff brought suit on behalf of her son who committed suicide while detained in jail.
  - The allegation was that he was denied necessary medications and their deliberate indifference to his needs was in violation of the 8th Amendment.
  - A lawsuit was brought against Corizon which was contracted to provide medical and health care services to the county jail.
  - Plaintiff sought “any and all reports evidencing any investigation into the death of any inmate at the…jail”
  - Court initially held that eight of the nine disputed documents, including deaths of four other inmates, were not privileged.

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

- In response to a rule to show cause as to why the four documents should not be produced the defendant, for the first time, asserted that they were privileged under the PSQIA.

- **Court's Decision**
  - Corizon argued that the reports were submitted to its PSO.
  - Affidavit states that documents were placed in Corizon's PSES, were "created for submission into Corizon's PSES" and that it "makes information available and reports information contained in its PSES at the request of its" PSO.
  - Court states that under the HHS PSO Guidance, with a citation to the Daley v. Teruel decision, the documents must be created "for the purpose of reporting" to a PSO which, in this case, Corizon did not assert.

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

— "Significantly, the Declaration omits seemingly critical details about the timing of the submission to the PSO, giving rise to a reasonable inference that these documents were reported to the PSO only after plaintiff's requested them in this proceeding. Whether or not this is true, what is certain is that Corizon has failed to demonstrate the necessary element of the claimed PSQIA privilege."

- It did not help that some of the documents were "made for the purpose of security legal advice."
- Court also says that "most of the documents that issued were created in the ordinary course of Corizon's business — providing and improving care."

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

- Court also found that the attorney's client work product privileged did not apply because the documents were created for the purpose of improving patient care and not in anticipation of litigation.

- **Impact and Takeaway**
  - This is an example of needing to meet all substantive and technical PSQIA requirements.
  - In this case, the affidavit was defective because it did not reference that the documents were created for the purpose of reporting to PSO and there was no evidence as to when the reports actually were reported.
  - There is no reference in the opinion as to whether the information was being treated as deliberations or analysis.
  - Be prepared for the "ordinary course of business" argument which, taken to its extreme, would totally undermine the PSQIA protections.
  - Emphasizes the need to educate the court regarding the PSQIA.

Impact and Lessons Learned

- **<u>Use Detailed Affidavits to Support Argument</u>**
  - The role of the provider and its legal counsel is to effectively educate the courts about the PSA so the judges have a better understanding as to the context as to why the disputed materials are PSWP.
  - As is true in most cases, courts rely heavily on the affidavits that were submitted to demonstrate compliance with the PSA requirements in order to determine whether the information qualified as PSWP.
  - All representations in an affidavit are accepted as true unless they are otherwise rebutted.
  - Sometimes multiple affidavits maybe required.

Impact and Lessons Learned

— The type of representations and documents to include within an affidavit include the following:

- The PSO AHRQ certification and recertification letters
- The provider's PSO membership agreement.
- The PSES policy.
- Citations to the policy where disputed documents are referenced and whether the information was reported to a PSO or treated as deliberations or analysis.
- Screenshots of the redacted forms, reports, etc., for which the privilege is being asserted.
- Documentation as to when the information was reported, either electronically or functionally, or when the information qualified as "deliberations or analysis" under this separate pathway.

Impact and Lessons Learned

- A description of how information is collected within the PSES, how it qualifies as PSWP, if not otherwise set forth in the PSES.
- Representation as to how the PSWP was or is used for internal patient safety activities and used by the PSO.
- Representation that the information has not been collected for unrelated purposes, such as satisfying a state or federal mandated reporting requirement but is being collected for reporting to a PSO.
- If possible, a representation that the provider is not required by state or federal law to make the information available to a government agency or other third party.

Impact and Lessons Learned

- An affidavit from the PSO acknowledging the provider's membership and that the information, if reported, was received and is being used to further the provider's and the PSO's privileged patient safety activities
- Make sure that use of outside experts used to conduct patient safety activities to benefit the hospital or PSO are correctly documented and use references in PSES. Considering including the engagement letter with PSES.
- Remember, risk management information and activities relating to claims and litigation support will not be considered PSWP.
- Assert other privilege protections if applicable.
- Policies are not privileged references.

Additional Litigation Lessons Learned and Questions Raised

- Types of Legal Challenges:
  - Timing of when provider connected with a PSO versus dates of the claimed privileged documents.
  - Did the provider and PSO establish a PSES? When?
  - Was the information sought identified by the provider/PSO as being collected within a PSES?
  - Was it actually collected and either actually or functionally reported to the PSO? What evidence/documentation?
  - If not yet reported, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect a practice or standard for retention?
  - Is the information being treated as deliberations or analysis?

Additional Litigation Lessons Learned and Questions Raised

- Has information been dropped out? Did you document this action?
- Is it eligible for protection?
- May be protected under state law.
- Is provider/PSO asserting multiple protections?
  - If collected for another purpose, even if for attorney-client, or in anticipation of litigation or protected under state statute, plaintiff can argue information was collected for another purpose and therefore the PSQIA protections do not apply – cannot be PSWP and privileged under attorney-client

Additional Litigation Lessons Learned and Questions Raised

- Is provider/PSO attempting to use information that was reported or which cannot be dropped out, i.e., an analysis, for another purpose, such as to defend itself in a lawsuit or government investigation?
  - Once it becomes PSWP, a provider may not disclose to a third party or introduce as evidence to establish a defense.
- Is the provider required to collect and maintain the disputed documents pursuant to a state or federal statute, regulation or other law or pursuant to an accreditation standard?
- Was the information being used for HR, claims management or litigation management purposes?

Additional Litigation Lessons Learned and Questions Raised

- Document, document, document
  - PSO member agreement
  - PSES policies
  - Forms
  - Documentation of how and when PSWP is collected, reported or dropped out
  - Detailed affidavits
  - Separate Attorney-client privilege protections
  - Independent contractor agreements
  - Utilization of disclosure exceptions

Additional Litigation Lessons Learned and Questions Raised

- Advise PSO when served with discovery request.
- Get a handle on how adverse discovery rulings can be challenged on appeal.

Significant Court Decisions

- Schlegel v. Kaiser Foundation Health Plan, No. CIV 07-0520 (E.D. Cal, October 10, 2008)
- KD ex rel Dieffenbach v. U.S., 715. F. Supp. 2nd 587 (D.Del. 2010)
- Morgan v. Community Medical Center Healthcare System, Penn. No. 2008-CV-4859 (Lackawanna Co. June 14, 2011)
- Illinois Department of Financial and Professional Regulation v. Walgreens, 2012 Il. App. (2nd) 110452
- Tibbs v. Bunnell, 532 SW 3rd 658 (Ky. Sup. Ct. 2014, cert. denied, 136 Sup. Ct. 2504 (2016)
- Tinal v. Norton Healthcare, Inc. (C.A. No. 3:11-CV-596-S (W. Dist. Ky., May 8, 2014).
- Johnson v. Cook County (No.15 C 741 (N.D. Ill., August 31, 2015)
- Baptist Health Richmond, Inc. v. Clouse, 497 SW 3d 759 (Ky. Sup. Ct. 2016)
- University of Kentucky v. Bunnell, 532 SW 3d 658 (Ky. Ct. App. 2017)
- Charles v. S. Baptist Hosp. of Fla, Inc. 209 So.3d 1199 (Fla. 2017) cert. denied 136 S. Ct. 2504 (2017)
- Daley v. Teruel and Ingalls Memorial Hospital, 2018 Il. App (1st) 170891

Michael R. Callahan

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed advice in all areas of hospital-physician relations and health care regulatory compliance including EMTALA, HIPAA the Medicare CoPs and licensure accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory policy and litigation standpoint including the development of patient safety organizations (PSOs).

Practice focus

- Federal and state licensure and accreditation for hospitals and health systems
- Hospital-physician relations including contracts, bylaws and peer review investigation and hearings
- PSOs and participating provider policies, compliance and litigation support
- CMS and state departments of health investigations
- Assisting health systems with medical staff integration

The knowledge to identify efficient and practical solutions

- Health systems, hospitals and physician groups large and small, across the country come to Michael for practical, real-world guidance and answers to challenging legal and operational issues which Michael can provide quickly because of his many years of experience. He understands the reality of hospital quality, peer review, risk management and related operational legal and regulatory complexities and can rely on a large client base in order to also provide better and comparative solutions.

Katten Locations

CHARLOTTE
550 South Tryon Street
Suite 2900
Charlotte, NC 28202-4213
+1.704.444.2000 tel
+1.704.444.2050 fax

CHICAGO
525 West Monroe Street
Chicago, IL 60661-3693
+1.312.902.5200 tel
+1.312.902.1061 fax

DALLAS
Comerica Bank Tower
1717 Main Street
Suite 3750
Dallas, TX 75201-7301
+1.214.765.3600 tel
+1.214.765.3602 fax

HOUSTON
1301 McKinney Street
Suite 3000
Houston, TX 77010-3033
+1.713.270.3400 tel
+1.713.270.3401 fax

LONDON
Paternoster House
65 St Paul's Churchyard
London EC4M 8AB
United Kingdom
+44 (0) 20 7776 7620 tel
+44 (0) 20 7776 7621 fax

LOS ANGELES – CENTURY CITY
2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

LOS ANGELES – DOWNTOWN
515 South Flower Street
Suite 1000
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

NEW YORK
575 Madison Avenue
New York, NY 10022-2585
+1.212.940.8800 tel
+1.212.940.8776 fax

ORANGE COUNTY
100 Spectrum Center Drive
Suite 1050
Irvine, CA 92618-4960
+1.714.966.6819 tel
+1.714.966.6821 fax

SHANGHAI
Suite 4906 Wheelock Square
1717 Nanjing Road West
Shanghai 200040
P.R. China
+86.21.6039.3222 tel
+86.21.6039.3223 fax

WASHINGTON, DC
2900 K Street NW
North Tower - Suite 200
Washington, DC 20007-5118
+1.202.625.3500 tel
+1.202.298.7570 fax