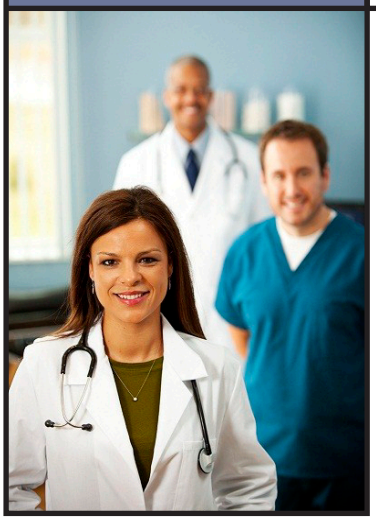


CLARITY PSO

A Patient Safety Organization

A Five-Year Report to Healthcare Providers

November 2013

www.claritypso.com

Preface

This is our inaugural report on the work of Clarity PSO. Clarity PSO was organized in 2008 at the dawn of the federal Patient Safety and Quality Improvement Act, which introduced the Patient Safety Organization (PSO) program. As a component PSO and independent operating division of Clarity Group, Inc., we officially listed as P0015 with the U.S. Department of Health and Human Services (HHS), Agency for Healthcare Research and Quality (AHRQ) on November 18, 2008, and relisted for our second three-year term through November 2014. We are proud to be a founding PSO in the patient safety movement and to serve the healthcare providers who contract with us for our insight and services that support their patient safety efforts.

The people who do the real work of healthcare, at the point of care and in the management of healthcare services, are the ones to be applauded; they have the courage to report issues and events and the willingness to change course, alter mental models of delivery and create the types of conditions that support a culture of change and a focus on safety. That is ***leadership***, and without them, no change is possible.

This report is intended to inform all healthcare providers of the founding principles and basic workings of the PSO program, and how contracting with a PSO can greatly enhance the risk-quality-safety efforts at a variety of organizations. We believe that what we do as a PSO has great benefit to sustainable and forever-enriched patient safety and healthcare quality. Our work is dedicated to that belief.

Tom Piotrowski, RN, MSN, CSSGB
Executive Director
Clarity PSO, a Division of Clarity Group, Inc.

Anna Marie Hajek
President & CEO
Clarity Group, Inc.

"Our organization was an early proponent of Patient Safety Organizations. In our five years with Clarity PSO, we have clearly seen the benefit of the overall comparative reports and are actively engaged in the ambulatory safety initiative where our physicians are playing a very active role in patient safety across our healthcare system."
- R. Timothy Rice, Chief Executive Officer, Cone Health, Greensboro, NC

A Brief History

Clarity Group, Inc. (Clarity) is a healthcare services company that specializes in the management of professional liability risk exposure through integrated risk-quality-safety (RQS) processes and tools. The principals at Clarity have worked in the medical malpractice environment for more than 35 years and have consistently operated their companies on the fundamental premise that to best protect against allegations of medical negligence, healthcare providers must focus attention on quality and safety. No harm, no claim, period. Clarity was formed 11 years ago, and with that philosophy and our years of experience, we have worked diligently with our healthcare clients across the country to adopt integrated RQS systems to help modify behaviors and mitigate risk exposures across the entire system of care.

In 2005, the Patient Safety and Quality Improvement Act (PSQIA) was signed into law. Clarity watched the development of this Act eagerly because we felt that our clients could benefit greatly by the principles described in the Act. Among other provisions, the Act outlined a system for the creation of Patient Safety Organizations (PSOs), whereby the open and transparent sharing of patient safety data would be used to help build a picture of national patient safety trends and awareness, and in exchange any data shared would be protected from discovery in litigation, by federal pre-emption, in the event of allegations of medical negligence against participating healthcare providers. In February of 2008, enabling guiding authority was released in the form of the Proposed Rule. After the comment period and when AHRQ was able to accept applications, Clarity immediately filed our listing for Clarity PSO.

Early Emphasis

At Clarity PSO, we were most interested in understanding the full ramifications of the PSQIA in terms of both responsibilities and benefits accruing to healthcare providers, and the full operating responsibilities of the PSO. From the start, we aligned our PSO with a variety of experts in the field to ensure that we were providing our clients with the benefits of a wide range of knowledge. We worked through the internal organizational aspects of being a component PSO to set up the appropriate firewalls and contingencies to guarantee the protection of any data, or Patient Safety Work Product (PSWP), reported into Clarity PSO. Then and now, we devote considerable resources to enhanced data security and operating policies to help ensure that appropriate data security protections are in place.

Beyond any internal processes, we recognized that our PSO clients needed to undergo their own organizational preparedness in order to learn how to work best with a PSO. In addition, while Clarity and Clarity PSO were very excited about the opportunities afforded to healthcare providers, the entire industry was at the time still largely unaware of the basic principles of the PSQIA and the implications of contracting with a PSO. In an effort to boost knowledge and awareness, Clarity PSO began a series of education initiatives through our website, white papers, presentations and webinars. With these initiatives, we wanted to help healthcare providers understand this powerful new tool to enhance safety provided by the PSQIA.

What the PSQIA Means to Healthcare Providers

- Aims to improve safety by addressing:
    - Fear of malpractice litigation
    - Inadequate protection by state laws
    - Inability to aggregate data on a large scale
- Creates Patient Safety Organizations (PSO) to assist healthcare providers in their patient safety activities
- Provides Federal legal privilege, as Patient Safety Work Product, and confidentiality protections to information collected for patient safety and healthcare quality enhancement purposes and assembled and reported by healthcare providers to a PSO or developed by a PSO to conduct patient safety activities
- Limits the use of patient safety information in criminal, civil, and administrative proceedings and imposes monetary penalties for violations of confidentiality or privilege protections

Working the PSO into the Client Organization…Not the Other Way Around

"Protect Your Protections"^{sm} is the mantra of Clarity PSO. From the beginning, Clarity PSO has had a consultative service structure that enables healthcare providers to organize their various risk-quality-safety resources into what is required under the Act, i.e., their own Patient Safety Evaluation System (PSES), which is the central construct for a provider to assert the protections under the PSQIA.

Our on-boarding process with clients focuses on the education and consultation needed to set up the right climate and organizational readiness to work with a PSO, paying close attention to other mandatory reporting obligations required of our clients (e.g., mandatory state reporting). That on-boarding process has helped our clients demonstrate due diligence for PSO reporting, prepare their policies and procedures, and articulate their PSES to get support from senior leadership and those closest to the point of care while also creating the documentation needed to help protect their protections under the PSQIA.

Patient Safety Evaluation System

Defined under the Patient Safety Rule for the PSQIA as a system in place at the provider and the PSO for the collection, management, or analysis of information for reporting to or by a PSO. The Patient Safety Evaluation System is the mechanism through which information can be collected, maintained, analyzed and communicated.

Data Reporting to the PSO

The Patient Safety Work Product (PSWP) protections afforded under the PSQIA are applied to data, analysis and reports that are intended for and then reported to/from the PSO. As part of the creation of an organization's Patient Safety Evaluation System, we work with our clients to determine the most applicable and eligible information that will be reported to the PSO and received from the PSO as PSWP.

Patient Safety Work Product

Defined by the PSQIA as: any data, reports, records, memoranda, analyses (e.g., RCA), or written or oral statements which could improve patient safety, healthcare quality or healthcare outcomes;

And that:
- Are "assembled or developed" by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a 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

Comparative benchmarking is a key element of the PSQIA, and to accomplish that, AHRQ created a set of common definitions and standardized reporting templates regarding patient safety events, i.e., the AHRQ Common Formats. The ultimate use of the Common Format data, when aggregated nationally, is to create the Network of Patient Safety Databases (NPSD) and establish a national benchmark for patient safety outcomes. The promise of a national error-reporting database brings great opportunities to improve patient safety nationally and Clarity PSO is among the early contributors of either test file data or live data to the NPSD.

Even with our earliest clients, data reporting to Clarity PSO began quickly, allowing us to promptly produce our first comparative reports. These reports were very high-level and demonstrated the need for comparable data collection to enhance their value and provide actionable information. Our clients saw this need, which helped accelerate the conversion to the use of the AHRQ Common Formats. As a PSO, we needed to attest to AHRQ that we had adopted a Common Format for reporting and we were successful in accomplishing that goal quickly.

At Clarity, we had already been using our own patient safety incident reporting tool, the **Healthcare *SafetyZone*® Portal**, with our captive insurance company clients since 2003. Before the passage of the PSQIA and the creation of Clarity PSO in 2008, the Portal was being used by scores of healthcare organizations. Data reported to Clarity PSO can come from any reporting system provided it is in the correct format, but for most of our new Clarity PSO clients, the Portal became the data collection tool of choice.

Moving the healthcare provider community to the Common Formats has been a challenge for PSOs in general, but Clarity PSO was fortunate to have our flexible data collection tool and a host of willing participants. These factors enabled us to work with our clients on converting to Common Formats while still allowing them to keep the personalization they desired in their reporting system.

The AHRQ Common Formats

- Standardized patient safety event information collected – common language and definitions
- Address all patient safety concerns: incidents, near misses, unsafe conditions
- Components of the Common Formats
    - Healthcare Event Reporting Form (HERF)
    - Patient Information Form (PIF)
    - Summary of Initial Report (SIR)
    - Event Specific Forms: Falls, HAI, Medication, Blood or Blood Product, Device or Medical/Surgical Supply Perinatal, Pressure Ulcer, Surgery or Anesthesia
- Setting specific: Hospital (in place); Readmissions (in testing); Long Term Care, Ambulatory (in development)

PSQIA and the Law – Will it Hold Up to a Court Challenge?

Healthcare providers, in assessing the value and long-term viability of the PSQIA often ask, "Will it withstand a court challenge?" or "Is there any case law that shows that PSQIA was upheld?" As with all new legislation, it takes time for case law to develop. In some early cases, the PSQIA was called on to protect the release of information, but unfortunately, the healthcare providers were not able to demonstrate their commitment to comply with the law's responsibilities to attain the protections. In those cases, the protection under the law was not upheld. There are recent cases, however, where the protections afforded to Patient Safety Work Product (PSWP) under the PSQIA have prevailed.

- In the first example, Illinois Department of Financial and Professional Regulation (IDFPR) v. Walgreens (Illinois, 4/7/11), the IDFPR issued subpoenas to Walgreens Company for the "incident reports of medication errors" on three pharmacists. Walgreens moved to dismiss the subpoenas stating that these reports were protected as PSWP under the PSQIA. The lower court upheld the protection, which was then appealed to the Illinois Appellate Court. Upon hearing the appeal, the Appellate Court upheld the lower court's opinion and the protections afforded to PSWP under the PSQIA were maintained.

- In a second case, Iasis Healthcare Holdings, Inc., which is a Florida based healthcare provider, was issued a motion to compel discovery of adverse medical incidents. By way of affidavit, Iasis asserted the privilege claiming the requested information was reported to a PSO. The trial court supported the claim and upheld the privilege stating that the PSQIA both expressly and impliedly pre-empts Florida state law Amendment 7. Motion to compel was denied.

- A third case involving one of our own Clarity PSO clients also recently revealed support for the assertion of the PSQIA protections. A community hospital was issued an order to produce information that was reported to Clarity PSO. After preparing supportive documentation, including contracts, PSES policy and affidavits, with our client, the circuit court judge upheld the hospital's protections as PSWP under the PSQIA for the requested incident reports and other materials sought by the plaintiff's counsel.

These decisions, particularly as they encourage a true culture of safety in error reporting, are most important to healthcare providers. The elements that supported the upholding of the privilege protections under the PSQIA are the critical steps that are woven into our clients' processes:

- Provide documentation that you as a healthcare provider have contracted with a PSO
- Demonstrate policies are in place regarding the identification of a PSES and functions of reporting of information, and a confirmation process that information was actually reported to the PSO
- Demonstrate procedures that recognize that PSWP information are only used within the PSO framework to support positive change, healthcare quality and patient safety improvement efforts

The Impact of the Patient Protection and Affordable Care Act (PPACA)

The passage of the Patient Protection and Affordable Care Act (PPACA) in 2010, and it subsequently being upheld by the United States Supreme Court in 2011, created a sea of change in the configuration of healthcare delivery systems. A fundamental principle of the PPACA is access to affordable healthcare and the creation of an insurance marketplace.

Part of the PPACA legislation outlines what may be expected of hospital providers who desire to work with the insurance marketplaces. Within the legislation, there is a provision that states that by January 1, 2015, hospitals with more than 50 beds that wish to contract with Qualified Health Plans in the Health Insurance Marketplace will need to have a PSES in place or they will be ineligible to participate as a provider in the health plan. The Act refers to Part C of title IX of the Public Health Service Act in its definition of a PSES, and as the Public Health Service Act was amended to include the PSQIA, it appears that this provision addresses the need to contract with an AHRQ-listed PSO to be in compliance. Several organizations are seeking clarification on this provision to know how it will apply to hospital providers and, it may be several months before this is known.

Regardless of the ultimate fate of the PPACA, the protections afforded by the PSQIA and its intent in promoting patient safety will not be affected. Each piece of legislation stands on its own merits, and healthcare providers and their patients gain a considerable advantage in the promotion of high quality and safe care through their participation with a PSO. In fact, many facets of healthcare that are not hospitals can gain protection and support for their quality efforts from the PSQIA and their participation with a PSO, while they often can gain neither under the various states' existing Medical Studies Acts or peer review protections afforded to hospitals.

Realizing the Potential of the PSQIA: Getting to Comparative Reports and Actionable Data

Patient Safety Organizations are required to perform Patient Safety Activities (PSAs) under the PSQIA. Our clients saw the benefits almost immediately through the actionable information that came via the data analytics and education provided by Clarity PSO. Provider members of Clarity PSO receive quarterly event reports that include current/historical and facility/aggregate data, which identify trends and patterns with regard to reported events. Clarity PSO and its Healthcare Advisory Council, a panel of clinical and patient safety experts from around the country, also provide analysis and recommendations to clients on a quarterly basis. The discovering, learning and sharing through multiple lenses allows for the development of safety initiatives and patient safety activities that can help lead to improved patient care outcomes.

Due to our initial success in getting our PSO clients to report data and our ongoing enhancement of the reports being generated, we are able to create a reporting template that provides strong insights into the operations of the individual client organizations. We make it a point to visit with AHRQ and help them understand the progress we and our clients are making. We are impressed with their dedication to patient safety and to the success of Patient Safety Organizations, and we are proud to have presented at the AHRQ Annual PSO Conference in both 2012 and 2013.

Going Beyond Comparative Data Reports

In addition to the comparative reports, the PSAs performed by Clarity PSO have yielded strong and positive insights and results for our client organizations. This table summarizes some of those PSAs and is followed by some of the changes that have been made because of these activities.

Patient Safety Activity	Purpose of Activity
Hospital Common Format Reporting	The concept in the development of the AHRQ Common Formats is that providers would be able to collect information and then conduct performance comparisons based on standardized data elements. As an early adopter of the Common Formats, Clarity PSO has been collecting events using these templates since 2011, which has allowed us to create comparative benchmarking reports.
Ambulatory Safety Initiative	A study of three data elements in relation to ambulatory care delivery: medical malpractice claims, a self-assessment survey and analysis of risk factors, and real-time event reports. The goal is to identify those areas of patient harm and potential errors outside the hospital itself to support a culture of safety across the healthcare continuum.
In-Camera Patient Safety Collaborative	Education session involving multiple provider types. Discussion of safety concerns occurring in their organizations and the industry. Focused education on how to develop a culture of safety. Our most recent collaborative was in relation to Nursing Peer Review best practices.
Policy/Procedure Review and Manual Creation	Critique and cross-map of policies, procedures and clinical protocols in a number of areas, such as moderate sedation, falls, medication administration and infection prevention. Identify best practices. Also created PSO safety manual for staff education and guideline.
Infection Control	Analysis and tool development to identify best practices in the prevention as well as surveillance of infections for national healthcare providers.

"As a leading provider of cloud-based radiology services, Radisphere takes great pride in ensuring the highest quality of patient care. We joined Clarity PSO so they could provide an objective review of our quality program and we take comfort in knowing we have a secure learning laboratory for our physicians and providers."
- Frank Seidelmann, DO, Chairman and Chief Medical Officer, Radisphere, Westport, CT

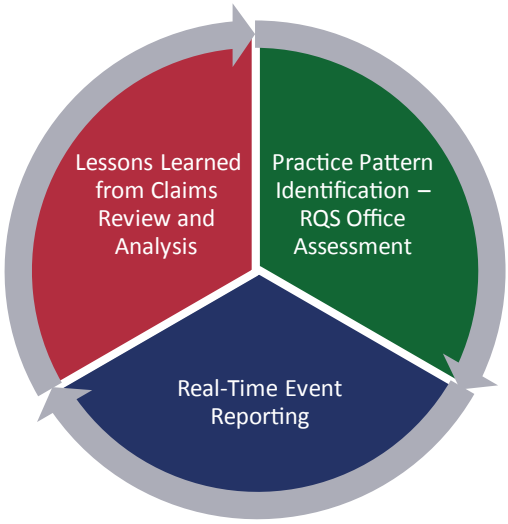
The changes that have been made due to our PSAs have involved review, analysis and development of several recommendations, and identification of best practices that have been adopted by our PSO provider participants. These include areas such as:

- Enhanced reporting of safety events including near misses and unsafe conditions
- Moderate sedation best practices
- Fall prevention protocol best practices
- Communication and hand-off best practices
- Error and Common Format reporting best practices
- Medical record documentation best practices

The nature of PSAs depends entirely on the specific provider type and/or specific situation in mind. In this way, activities are tailored to the client's environment of care and overall quality initiatives. The true power of the PSO is aligned with Clarity's fundamental philosophy of creating a spiral of positive change. The PSO helps providers have a heightened awareness of potential harm, creates a way to take a system-wide view of events that may be happening, accelerates decision making in terms of needed interventions, and supports sustainable change over the long term.

SPOTLIGHT: Ambulatory Safety Initiative

As the healthcare landscape continues to evolve with healthcare reform, Clarity and Clarity PSO have launched the Ambulatory Safety Initiative to gain insight into the quality and safety of care in the ambulatory setting and to identify key touch points where patients may be at risk of harm.



The Ambulatory Safety Initiative is comprised of three important aspects of outpatient service delivery: historical professional liability claims experience, a risk-quality-safety office practice survey and the establishment of a real-time event reporting system to capture safety events.

Analysis of reported safety events, RQS assessments, and closed claims activity are conducted to identify trends, patterns, and common themes related to patient safety in the ambulatory setting. The premise is to focus on the key elements of risk exposure in these three areas and identify and prioritize an organization-specific safety program that can be monitored over time.

Goals of the Initiative:

- Improve awareness of those areas of greatest risk for harm in ambulatory care
- Provide means to create and implement tools and strategies that improve the overall care delivered in the ambulatory setting
- Identify opportunities and similarities between hospital and ambulatory settings to improve quality and safety across the entire health system

Clients from Every Corner of Healthcare

Clarity PSO is working with hospitals and many other types of providers nationally. We believe our patient safety activities are enriched by this broad client base, and we look forward to continuing to work closely with our clients, which include:

- Integrated Health Systems
- Acute Care Hospitals
- Physician Groups
- Specialty/Sub-Specialty Providers
- Professional Societies

"We have been a Clarity PSO client since 2010, and through our collaborative work, we have been able to engage our organization in positive patient safety discussions from the direct point of care of our clinics to the medical management of our patients nationally."
- Greg Trulove, Assistant General Counsel, Risk and Litigation, DaVita Healthcare Partners Inc., Denver, CO

The Time is Now!

Clarity PSO is proud to be working as a PSO on behalf of healthcare providers across the country. We believe that the concept behind the PSQIA has been proven, and that with the emergence of new healthcare configurations and new payment structures based on quality of care delivered, the trajectory to create even greater benefits is steep and accelerating. The creation of the PSQIA paved the way for all providers to have a true learning laboratory to investigate harm and the potential for harm and to promote interactions that can change the entire safety picture for improved patient outcomes.

The benefits of contracting with a PSO have come into focus. Get the most out of your existing resources by focusing attention on the areas where the data suggest it is needed most. Increase knowledge sharing and awareness building in a safe place protected from discovery. Take a system-wide view of events that may be happening, accelerate decision making in terms of needed interventions, and support sustainable change over the long term. Enhance your culture of safety and watch it spread throughout your organization.

Working with Clarity PSO, healthcare providers have the power to move from repeat errors that eventually cause harm to a more predictive modeling process that can determine where the potential for harm exists and can be mitigated. We embrace our role as a part of this exciting movement, partnering with providers across the country to continuously foster excellence in patient care and safety in all healthcare delivery settings.

Advantages of Working with Clarity PSO

- Consultative process designed to allow the PSO to adapt to your organizational processes
- "Protect Your Protections"℠ on-boarding process
- Resource extension of your own quality and patient safety efforts
- Focus on the continuum of care across expanding healthcare organizations
- Access to a nationally recognized group of clinical and patient safety experts through our Healthcare Advisory Council
- Patient Safety Activities tailored to your organization's needs
- Common Format Reporting for standardized benchmarking of clinical areas
- Experience with many facets of healthcare delivery brings a broad view to how patient safety and healthcare quality are addressed by many types of healthcare providers

About Clarity PSO

Clarity PSO is a federally listed Patient Safety Organization with the Agency for Healthcare Research and Quality and stands as an independent division of Clarity Group, Inc. Clarity PSO offers healthcare providers a full range of solutions for increasing patient safety, including analytical benchmarking, risk-quality-safety resources and systems development. Clarity's team of PSO consultants is dedicated to helping healthcare providers of all kinds mitigate risk while improving the quality of care.

For more information on Clarity PSO, visit:
www.claritypso.com or call us at 773-864-8280

For more information on PSOs, visit:
www.pso.ahrq.gov