CLARITY PSO

A Patient Safety Organization

# PSO Impact and Opportunity

## A Seven-Year Report to Healthcare Providers

October 2015

www.claritypso.com

## *Preface*

This is an update to our initial report, *Clarity PSO – A Five-Year Report to Healthcare Providers*, published in November of 2013. In the two (2) years since that inaugural report, Clarity PSO has continued to engage with many healthcare providers from a variety of healthcare service areas. We have seen an increase in commitment to the tenets of the Patient Safety and Quality Improvement Act (PSQIA) that created the Patient Safety Organization (PSO) program in 2008, and the impact that working with a PSO can have on providers and their delivery of care.

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 a window into the work of Clarity PSO, and more importantly, the insights that our clients have gained through their work with Clarity PSO. Healthcare providers and the federal government remain committed to enhancing the safety of our healthcare delivery system, and both are seeing the impact that PSOs can have on achieving that goal. We are proud to be a founding PSO and to serve the healthcare providers who contract with us for our products, services and insights. We continue to 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.

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## *What is a Patient Safety Organization (PSO)?*

By way of introduction to this report, PSOs are the product of the Patient Safety and Quality Improvement Act of 2005 (PSQIA). This Act called for the creation of entities (PSOs) to help healthcare providers in assessing and improving patient safety outcomes in the U.S. healthcare delivery system. The statutory provisions were designed in such a way that they encourage all licensed providers to collect and report patient safety and quality information to a federally listed PSO. In return, all data reported to the PSO are protected as privileged and confidential.

A PSO creates a learning lab for healthcare providers and allows them to participate in patient safety activities (PSAs) and share sensitive information without the fear of liability. The protected information, which is referred to as Patient Safety Work Product (PSWP), includes any data, reports, analyses, or written or oral statements, etc., that are developed for reporting to a PSO. The ability to examine PSWP and conduct PSAs gives healthcare providers the tools they need to reduce patient safety errors and improve healthcare outcomes.

**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 (PSOs) 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

*"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*

## *Clarity PSO - Who We Are and What We Do*

During the early years, Clarity PSO began by providing awareness and education to providers and stakeholders on how to align their organizations and benefit from their work with a PSO. The program has transformed far beyond simple awareness and education. Today, the providers and stakeholders that we have worked with have gained tremendous insights into the benefits of contracting with a PSO and are now incorporating the learnings obtained from the PSO into their operations.

Over the past seven (7) years, Clarity PSO has engaged healthcare providers in deeper, more meaningful ways. Both our work and our team have progressed, and the nature of how we advance patient safety has transformed. Clarity PSO has expanded on many fronts: clinical, analytical and operational. Our broad client base continues to be a strength as it allows us to connect and work with a wide range of provider types. We have refocused our efforts regarding Common Format reporting, and we have grown tremendously in our specialty services, which include radiology, dialysis, ambulatory care, Federally Qualified Health Centers (FQHCs), large physician groups, and outpatient surgery centers. We also celebrated the one-year anniversary of the radiation oncology safety program, the Radiation Oncology Incident Learning System™ (RO-ILS), sponsored by the American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM), and underpinned by Clarity's Healthcare *SafetyZone*® Portal software for event reporting. In addition to the many direct clinical provider activities, Clarity PSO has also continued to support and assist fellow PSOs in various aspects of program participation, including the development of internal and provider policies and procedures; safety event reporting and analysis; and interpretation of safety event findings with tailored recommendations for improvement.

Today, the services that Clarity PSO offers build upon our history and continue to raise the bar, not only for us internally, but also for other PSOs in the community. Clarity PSO has set a leadership example within the PSO community and continues to forge ahead striving for innovation and insight within patient safety.

## *Conducting Patient Safety Activities*

Clarity PSO assists providers in bridging the gaps and silos that occur in care delivery by focusing on the health of the organizational culture and by encouraging communication among different types of providers. This is accomplished in many ways:

- Group-think activities involving different forms of analytics
    - Root Cause and Common Cause Analysis
    - Failure Mode Effects Analysis (FMEA)
- Benchmarking and Comparative Analysis
- Simulation Exercises

Our clients have benefited greatly from the various forms of analytics and patient safety activities (PSAs) afforded by the PSO program. Our PSAs are tailored to each client and have yielded strong and positive results. Through our clinical experts, we have been able to cut across a number of issues at all levels of an organization. The following are examples of some of our patient safety activities, which take the form of clinical, operational, and even cost analysis of care delivery.

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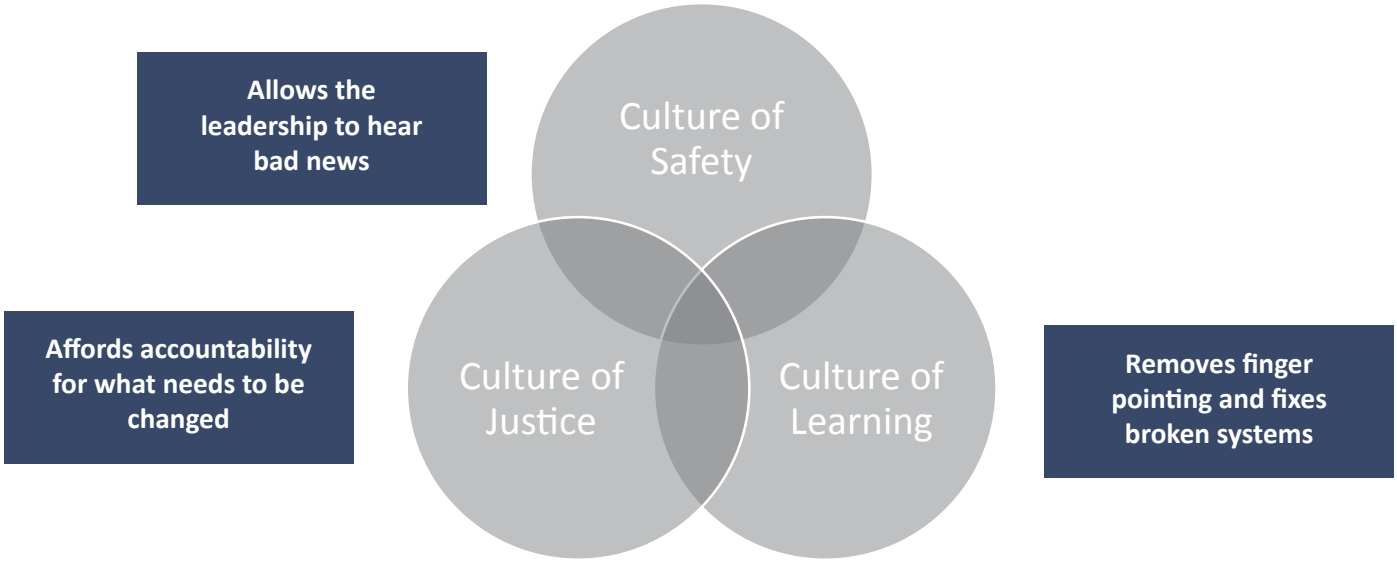
| Near-miss Reporting | In-camera Patient Safety Collaborative | Long Term Care Reporting |
| Radiology Mis-read Analysis | Policy/Procedure Review and Manual Creation | Pediatric Dialysis Standards |
| Ambulatory Safety Pilot | Infection Prevention Project Collaborative | Fall Prevention Deep Dive |
| Behavioral Health Event Analysis | AMA Event Analysis | HIT-related Event Analysis |
| Nursing Peer Review | Moderate Sedation | Medication Error Deep Dive |

Chief among the accomplishments for which we are most proud is the submission of our data to the Network of Patient Safety Databases (NPSD). The NPSD was developed to "create a learning system for quality improvement strategies for PSOs and healthcare providers." The NPSD is the intended repository for national data, but to date, only nine (9) patient safety organizations of the 81 federally listed have sent data to the NPSD, and Clarity PSO is one of them. While always striving to break new ground, we aim to remove and/or mitigate any and all barriers to patient safety, and with our dedication to analyze, educate, and evolve this industry, we can and will continue to make culture change and patient safety our focus.

**Creating and Supporting a Culture of Safety**

Clarity PSO is devoted to creating an environment in which errors and mistakes can be openly analyzed with the foundational understanding that it is important to learn from these events in order to achieve the safest and highest quality patient care. Creating a safe culture is arguably the most difficult work that we have been called to accomplish in healthcare. As safety analysts, we often ask providers to "show us their safety culture." The questions remain: How do you show and describe a safe culture? Would you know it if you saw it? Does it exist only in certain parts of an organization? The PSQIA Final Rule Regulations spell out that one of its primary intents is to "foster a culture of safety." For Clarity PSO, this is the core tenet of all that we do for our clients and providers. We describe a safe culture as having three parts: Culture of Safety, Culture of Justice and Culture of Learning.




Derived from the work of some of the world's fundamental safety culture experts such as James Reason, David Marx, Sidney Dekker, and others, Clarity PSO's work and approach to safety culture includes several strategies. First, it is critical to understand the level of engagement within the organization as well as within its components. A safety culture begins and ends with leadership and front-line staff. Anything else often results in failure, and in this *begin-end* way, the journey to a safe culture is disseminated and solidified throughout the entire organization.

To create awareness, Clarity PSO deploys specific strategies such as the use of simulation exercises. Our clinical analytics team includes expertly trained nurses who specialize in leadership and simulation. We are able to re-create clinical scenarios that allow providers to openly and safely critique what they could have done better. Other tools Clarity PSO has developed include checklists and toolkits that establish starting points and evaluative points for the creation and maintenance of a safe culture.

Providers nationwide are engaged in the pursuit of a culture of safety. Working with a PSO gives a healthcare provider a focused resource and a set of tools to help establish the internal transparency needed to transform its organization into an environment where safety is placed at the core of all that it does. Working with a PSO also provides the organization with a "learning laboratory" and a safe environment where errors can be studied, and unsafe conditions can be explored and changed. The PSO provides the data analytics, objective review capabilities, and insights to support the very culture that the leadership is striving to attain.

**Using Data and Reports**

One of the key aspects of a successful PSO program is the reporting of safety events. Consistent and complete safety event reporting remains a challenge in healthcare, but without reporting, PSOs cannot do necessary safety analysis. In order to promote incident reporting, Clarity PSO has led the charge by providing easy reporting options (functional and direct reporting) as well as world class analytical applications. We often hear from the PSO community that PSOs who are less efficient suffer from (1) having no processes to easily transfer reported information to the PSO or (2) do not know what to do with the data reported to them. We were one of the first PSOs in the country to present a de-identified Aggregate Common Format Report to AHRQ, and continue to advance reporting and analytics in the PSO community.

In an attempt to reduce errors across the nation, it is necessary for healthcare providers to share learnings and insights accrued from reported errors. It has been our objective to remain in close contact with our clients to understand their healthcare delivery environments and learn about their wants and needs. As such, we are able to (1) encourage deep and robust reporting and (2) understand, use, and translate the data back to our clients in meaningful projects. By understanding the clinical atmosphere, a bridge can be forged to bring the data back to the clients in ways that may not have been considered. Far too often, providers spend too much time trying to organize and decipher their data in order to create valuable information from which they can develop an action plan. Clarity PSO's clinical and data analytics team does this for our clients so they can focus their attention on their patients and not a pile of data. The tangible learnings provided by Clarity PSO can take various forms including quarterly reports, deep dives or focused analyses projects, and our PSO Learning Series Reports.

Our data reporting goals are to allow for:

- Timely data, in order to create and initiate relevant action plans in response to recent events. Each report is derived from a deep examination of the corresponding aggregate and individual provider database. For example, a recent report examined the pressure ulcer database and extracted data evidence related to patients that developed suspected deep tissue injuries even after those patients were identified as being at risk for developing a pressure ulcer. Delivering this information quickly was vital to removing other patients and residents from harm's way.

- Trending data, in order to create a picture of performance and understand the full scope of patient safety. Each client is given an overview of performance and is compared with like providers. In this way, our clients can identify where they have growth opportunities and where they have best-in-class practices.

- Collaboration with the community. Once a best-in-class practice has been identified, Clarity PSO arranges for providers to connect with each other and share both the successes and pitfalls for a given safety strategy.

The process for developing these reports and producing tangible learnings starts with diving deep into the data and asking questions, with the most important being "what does this mean for the provider?" A combination of discussions with providers and our clinical experts as well as a literature review propels the investigation deeper into the knowledge that exists outside of the database, within both the clinical and academic worlds of healthcare. Based on the discussions, literature review and data investigation, we are able to provide recommendations that are tailored to the themes seen within the reported safety incidents.

Much of what we learn comes not only from the data analytics themselves, but also from the interactions that we both witness and participate in amongst various providers. While each and every organization is unique with substantial environmental differences, there are universal themes at the core of errors and mistakes. The fundamental failures of upholding safety are not always specialty-specific. Reported event data have identified themes such as communication failures, distractions, rushing, multi-tasking, etc., across many areas of healthcare delivery and not just in one specific provider type.

*"We are proud and eager to continue our journey as a PSO and remain committed to working closely with the healthcare community on advancing the quality of our nation's healthcare delivery. The benefits of the PSO program are significant, and it is our mission to offer the industry's leading capabilities through this important vehicle."*
*- Tom Piotrowski, Executive Director of Clarity PSO*

## *PSO Impact on Providers - Spotlight on Progress in Patient Safety*

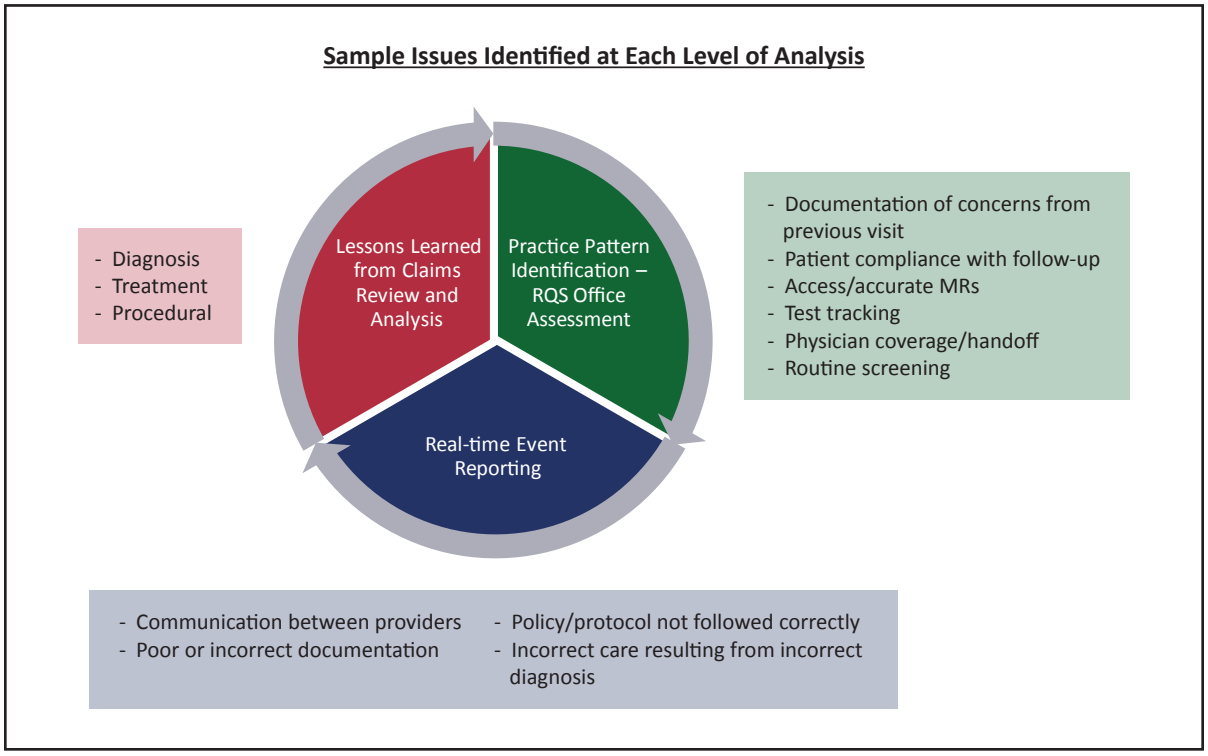
The following are real examples of how patient safety activities helped our clients implement changes at their organizations and ultimately led to safer care delivery practices and processes.

**Safety in Ambulatory Settings**

Clarity and Clarity PSO launched the Ambulatory Safety Initiative (Clarity ASI) in 2012 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.

Clarity's strategy for the Initiative hinges on a triangular analysis of three focus areas: (1) closed claims analysis; (2) evaluation of office practice assessment surveys; (3) real-time safety event reporting analysis. We have been able to gather and analyze data from the triangular analytics and identify targeted areas of focus that allow providers to take a more proactive approach to implementing strategies for safer care. Due to the success of the Initiative, providers are now implementing strategies such as:

- Creating a process centered on health screening guidelines
- Maintaining an updated medication list
- Reviewing and revising protocols for missed appointments to include follow-up and medical record documentation
- Developing a formal documentation process for a physician's review of test results, consultation reports, etc.
- Developing a standardized system for documenting allergies
- Developing a documentation process for unresolved patient problems and issues from prior office visits
- Developing protocols for tracking prescribed tests and procedures and recommended follow-up appointments

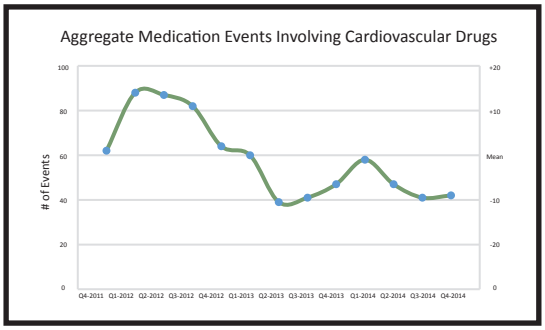



**Handoffs and Patient Safety**

This analysis examined how critical communication is during all aspects of care delivery. Through data analytics, Clarity PSO identified an especially vulnerable time in the care process that resulted in patient falls, injuries and other risk exposures. In particular, we examined the point at which patients leave their hospital rooms and travel to another part of the hospital. Communication and a proper handoff are crucial at this time due to the relinquishment of patient care to another provider. The analysis allowed best practices to emerge in what is commonly called a safe "Ticket to Ride." What resulted from this was ultimately a re-development of organizational standards within the falls prevention program, which are now routinely practiced when patients leave their rooms for additional care such as tests and procedures.

**Medication Administration Analysis**

This is a success story in which Clarity PSO assisted providers in identifying that a large number of medication events involved cardiovascular drugs. Through our continuous examination of trends and themes within the PSO database on medication events, it was noted that cardiovascular drugs were the third leading classification involved in errors at the time. A report was created for our providers depicting this information. The providers then implemented strategies surrounding the use and control of cardiovascular medication processes. The result was a marked decrease in events that involved cardiovascular drugs. As of Q2 2015, cardiovascular drugs have dropped from the third leading classification to the fourth leading classification of medications involved in errors. In other words, cardiovascular drugs have become less of a risk to patient safety.




## *Where We Are Headed - A National Repository and Patient Safety Collaboration*

While it is not feasible to describe every learning and every safety event that Clarity PSO reviews, this report offers several ideas and directions toward a better safety culture. It is our hope that we continue to move forward and further the accomplishments of the PSO program including the establishment of the NPSD and additional collaboration with PSOs.

**National Database Reporting**

This is a call to action for both PSOs and providers. The NPSD is the repository created to bring event analysis to a point where it can be used nationally, but data reporting into the NPSD has been slow to develop. To encourage better and greater data collection, we must:

- Make reporting easy and in line with clinical workflow at the organizational level. This includes fostering the right culture and obtaining the right reporting tools
- Offer incentives for more reporting, not punishments for coming forward
- Offer easy and straightforward ways to validate, analyze, and trend safety event information from provider to PSO to provider to national database and back to the provider

**PSO and NPSD Collaboration**

This would include and combine data sources at the PSO and national levels to allow for more sophisticated analysis including predictive modeling and surveillance, which will be critical tasks considering the many forms of data collection and error identification. Today there are a few databases and outcome registries, but we have yet to create a safety database.

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

Part of the PPACA legislation outlines what may be expected of hospital providers who desire to work with the insurance marketplaces. The Centers for Medicare and Medicaid (CMS) have confirmed that within the legislation, there is a provision that states that hospitals with more than 50 beds that wish to contract with Qualified Health Plans in the Health Insurance Marketplace will need to have a Patient Safety Evaluation System (PSES) set up or they will be ineligible to participate as a provider in the health plan. A Patient Safety Evaluation System is 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 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. CMS has confirmed that this provision addresses the need to contract with an AHRQ-listed PSO in order to be in compliance, and that it will be necessary for hospital providers to have this in place by January 1, 2017.

Regardless of the ultimate fate of this provision in 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. Many of our clients are not hospitals, so participation with Clarity PSO provides them protection and support for their quality efforts from the PSQIA. Generally, these healthcare organizations do not receive protections under the various states' existing Medical Studies Acts or peer review protections currently afforded to hospitals.

## *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 component PSO and independent operating division of Clarity Group, Inc. We 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 have been relisted for the second consecutive three-year term through November 2017. 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.

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