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The Patient Safety Organization Program: Key Barriers Impeding Nationwide Progress Toward Reducing Patient Harm in Hospitals

REPORT HIGHLIGHTS

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Why OIG Did This Review

Despite nationwide efforts to improve patient safety, patient harm events in hospitals remain a serious concern. Over nearly 20 years, OIG has identified persistently high patient harm rates nationwide in hospitals, nursing homes, and other health care settings.[1] The Patient Safety Organization (PSO) program is overseen by AHRQ and was the key provision of the Patient Safety and Quality Improvement Act of 2005 to improve patient safety on a national scale.

What OIG Found

The PSO program has fallen short in facilitating patient safety learning and improvement on a national scale. Although PSOs have helped some hospitals and health systems improve, OIG identified key challenges that hold the program back from achieving the progress envisioned in the Patient Safety and Quality Improvement Act of 2005.

Limited Alignment with Other Patient Safety Efforts: The PSO program could be better aligned with other efforts to improve patient safety, including research. Patient harm definitions vary widely, making it difficult to aggregate events and to analyze nationwide trends.

Uncertainty About Legal Protections for Hospitals That Work with PSOs: Continued uncertainty around legal protections (e.g., confidentiality) for patient safety data makes some hospitals reluctant to share these data for national learning and improvement.

Lack of Patient and Family Involvement: Under the PSO program, PSOs and hospitals have not meaningfully worked with patients and families, who can be valuable partners in patient safety.

Missed Opportunities to Leverage Newer Technologies: The PSO program has not fully harnessed newer technologies, such as artificial intelligence that could help overcome barriers that impede the effectiveness of the PSO program's Network of Patient Safety Databases (NPSD).

What OIG Recommends

1. Increase alignment of the PSO program with other HHS patient safety efforts
2. Promote opportunities to involve patients and families in PSO activities
3. Clarify cybersecurity protections and data use limitations for patient safety work product submitted to the NPSD
4. Take steps to harness technologies and new data sources that could help address barriers facing the NPSD

AHRQ concurred with all four of our recommendations.

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BACKGROUND

OBJECTIVES

1. To determine the extent of hospital participation in the PSO program
2. To identify opportunities to improve the effectiveness of the PSO program

Despite nationwide efforts to improve patient safety, patient harm events in hospitals remain a serious concern.[2] OIG found that 27 percent of hospitalized Medicare patients experienced patient harm events in 2008.[3] Ten years later, rates remained persistent, with OIG finding that 25 percent of hospitalized Medicare patients had experienced a harm event in 2018.[4]

The Patient Safety Organization (PSO) program is the U.S. Department of Health and Human Services' (HHS's) flagship program for facilitating patient safety event reporting and learning on a national scale.[5] However, in the years since the PSO program began in 2005, OIG work has raised concerns about persistent patient harm in hospitals, which suggests that the PSO program may not be reaching its full potential. There has been little improvement in the rate of patient harm events, and hospitals struggle to identify these events.[6]

This issue brief draws on OIG's body of work in patient safety and identifies challenges and gaps that prevent PSOs from playing a larger, more effective role in advancing patient safety in hospitals. We present our findings as a synthesis of key insights that patient safety experts, industry insiders, hospitals, and PSOs shared with us during this study.

The Patient Safety and Quality Improvement Act of 2005

Prompted by recommendations from the Institute of Medicine's 2000 report *To Err Is Human: Building a Safer Health Care System*, the Patient Safety and Quality improvement Act of 2005 (the Patient Safety Act, or the Act) sought to address longstanding problems with patient harm.[7, 8] A key provision of the Patient Safety Act is the PSO program, one goal of which is to facilitate a national patient safety reporting and learning system.[9] Providers, including hospitals, may choose to work with PSOs to report and analyze patient safety events, including harm. The PSO program is voluntary: Providers choose whether and how to work with a PSO. To reduce provider concerns about liability and encourage reporting, the Patient Safety Act established confidentiality and privilege protections for information that providers report to PSOs.[10] The Agency for Healthcare Research and Quality (AHRQ) oversees the PSO program.[11] In 2008, AHRQ published the Patient Safety and Quality Improvement Act Final Rule (the Patient Safety Final Rule) to implement the program, and organizations began to operate as PSOs.[12]

Patients and families as partners in patient safety

In the years since the enactment of the Patient Safety Act, clinicians, researchers, and others have increasingly recognized patient and family involvement as a tool to improve patient safety.[13, 14] Patients and families can engage with their providers to identify harm events and help analyze them, which supports a deeper understanding of harm and how to prevent it. For example, patients might participate in root cause analysis after they experience a harm event. AHRQ has also encouraged patient involvement in patient safety work, including the Communication and Optimal Resolution (CANDOR) process, which helps clinicians communicate with patients about harm events.[15]

PSOs

PSOs are private organizations or public entities (excluding health insurers; accreditation or licensing entities; or regulators, among others) that contract with hospitals and other providers to conduct patient safety activities.[16, 17] PSOs may be for-profit or nonprofit and may focus on a single provider type or clinical area, or work across provider types and clinical areas. PSOs are not Federal contractors and do not receive Federal funding for their work as PSOs.[18] To be Federally listed as a PSO (a process called initial listing), a PSO must be able to perform certain patient safety activities, such as analyzing patient safety data and developing best practices (see Appendix A for a full list of the required patient safety activities).[19] Every 3 years, PSOs must certify that they still meet the criteria to remain a Federally listed PSO (a process called continued listing).[20]

Individual PSOs have contributed to patient safety learning and improvements at their member hospitals according to studies that demonstrated the effectiveness of

specific approaches or interventions.[21, 22] However, there is little research on the effectiveness of the PSO program broadly to improve patient safety nationwide.[23]

Patient Safety Work Product (PSWP) and Legal Protections

Patient Safety Work Product (PSWP) includes data or analysis that a provider collects or creates to report to the PSO (and that is in fact reported to the PSO) that could result in improved patient safety, health care quality, or health care outcomes.[24] The Patient Safety Act excludes from the definition of PSWP a patient's medical record; billing and discharge information; or any other original patient or provider information. PSWP is protected under the Patient Safety Act's privilege and confidentiality provisions.[25] PSWP is not subject to subpoena or discovery in legal proceedings (with limited exceptions). The HHS Office for Civil Rights (OCR) is responsible for interpreting and enforcing the confidentiality provisions of the Patient Safety Act, including PSWP.[26]

PSWP can be disclosed in limited circumstances

The Patient Safety Act provides for some exceptions to the PSWP confidentiality protections. Specifically, 42 U.S.C. § 299b-22(c)(2)(C) **allows for disclosure of PSWP to "grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research** to the extent that disclosure of protected health information would be allowed for such purpose under the [Health Insurance Portability and Accountability Act] confidentiality regulations."

Network of Patient Safety Databases (NPSD)

The Network of Patient Safety Databases (NPSD) is a voluntary reporting system that aggregates patient safety data from PSOs.[27] The mandate of the NPSD is to analyze national and regional statistics, including trends and patterns of health care errors.[28] To submit data to the NPSD, PSOs must use AHRQ's standardized reporting definitions, known as the Common Formats. To facilitate national learning on patient safety, AHRQ publishes NPSD data and analyses in chartbooks, online dashboards, and other reports.[29] The NPSD accepts reports about incidents (patient safety events that reach a patient), near-misses, and unsafe conditions.[30] However, PSO participation in the NPSD is low; from 2010 to 2022, between 3 and 13 PSOs submitted data to the NPSD each year. In 2023, about half of the PSOs that reported working with hospitals (23 of 44 PSOs) collected data in the Common Formats, making them eligible to submit data to the NPSD.

The PSO Privacy Protection Center (PSOPPC) is AHRQ's contractor that receives PSWP that PSOs submit to the NPSD and renders data nonidentifiable for use in analysis

and public reporting. Neither AHRQ nor other HHS agencies have access to identifiable PSWP submitted to the PSOPPC.

AHRQ's Oversight of the PSO program

AHRQ implements key provisions of the Patient Safety Act, including the PSO program. AHRQ certifies and lists organizations as PSOs and can de-list PSOs. AHRQ may de-list a PSO for cause, for example, if the PSO does not meet the requirements in the Patient Safety Act, such as being able to perform core patient safety activities. However, the agency's authority over PSOs is limited. AHRQ cannot require PSOs to participate in key aspects of the PSO program, such as submitting data to the NPSD.

AHRQ offers technical assistance to PSOs and providers to help them understand the PSO program, including the Patient Safety Act, the Patient Safety Final Rule, and PSO activities. The agency also collects data about PSO characteristics and the providers that work with PSOs through an annual voluntary survey.

In March 2025, HHS announced that AHRQ will merge with the Assistant Secretary for Planning and Evaluation (ASPE) to create the HHS Office of Strategy "to enhance research that informs the Secretary's policies and improves the effectiveness of Federal health programs."[31] This report refers to AHRQ prior to the restructuring, and our recommendations are directed to AHRQ until HHS completes creation of the Office of Strategy.

Related OIG Work

This study builds upon a 2019 OIG report that found that over half of acute care hospitals worked with a PSO and that nearly all of those hospitals found this relationship valuable.[32] The report also found that hospitals and PSOs faced challenges in understanding the PSO program's legal protections, adopting the Common Formats, and submitting data to the NPSD. In response to OIG's three recommendations in the report, AHRQ developed and executed a communications strategy to increase hospitals' awareness of the PSO program and its value to participants, and updated guidance for PSOs on the initial and continued listing processes to be Federally recognized as a PSO. Although AHRQ concurred with OIG's recommendation to encourage PSOs to participate in the NPSD, it did not concur that AHRQ should accept data into the NPSD in other formats in addition to the Common Formats. However, AHRQ conducted a pilot study to explore the feasibility of analyzing free-text data that was already in the NPSD (contained within the Common Formats' free-text fields).[33]

Prior OIG work has also found persistent rates of patient harm across hospitals and other health care settings, with a quarter of hospitalized Medicare patients experiencing some form of harm.[34] A followup report released in 2025 found that hospitals failed to capture half of these harm events (49 percent) in their incident reporting or other surveillance systems.[35] Most sampled hospitals stated they

worked with PSOs, but given that hospitals did not capture about half of the patient harm events that occurred in their facilities, hospitals may be limited in providing information to PSOs for learning. OIG recommended that AHRQ and the Centers for Medicare & Medicaid Services (CMS) align patient harm event definitions and create a taxonomy of patient harm to drive a more comprehensive capture rate of harm events. OIG further recommended that CMS (1) ensure that surveyors prioritize the Medicare Quality Assessment and Performance Improvement requirement to hold hospitals accountable for patient harm, and (2) instruct Quality Improvement Organizations to use information about harm events to assist hospitals in identifying weaknesses in their incident reporting or other surveillance systems.

Methodology

Data Sources

AHRQ survey of PSOs. We requested survey data from an annual voluntary survey that AHRQ uses to collect data about PSO characteristics and activities. We requested survey data from 2023, which was the most recent year of data at the time of our review. We also requested the names of all PSOs listed during 2023.

Interviews. We conducted interviews with five PSOs, four hospitals, patient safety experts, and officials from AHRQ. We interviewed patient safety experts from two patient safety advocacy organizations and two research institutions, and one with experience advising hospitals and PSOs on legal matters related to the Patient Safety Act. We selected PSOs with different characteristics (e.g., number of member hospitals or clinical focus). Likewise, we selected hospitals with different characteristics (e.g., geographic location, bed size). For our interviews with PSOs, we spoke with staff on the PSO leadership team. For our interviews with hospitals, we spoke with administrators or clinical staff who were familiar with the hospital's work with PSOs.

Data Analysis

AHRQ survey of PSOs. We analyzed data from AHRQ's annual survey of PSOs and the PSOs listed during 2023 to determine the survey response rate. We analyzed PSOs' responses to the 2023 survey to describe characteristics of PSOs and their work with hospitals.

Interviews. We analyzed interview data to identify common themes related to successes and challenges in the PSO program, as well as opportunities for greater impact. Some interviewees provided supporting documentation, which we analyzed to identify common themes.

Limitations

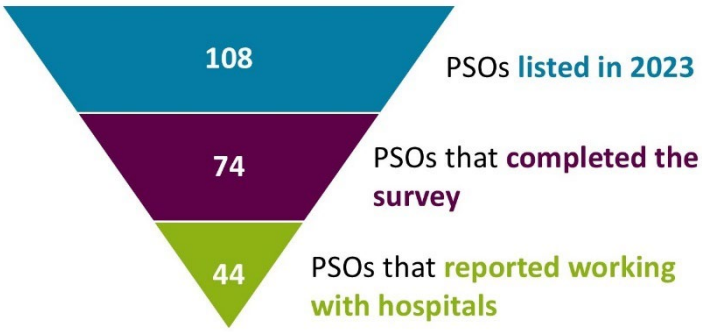
We did not independently verify all information from our interviews. Our findings on AHRQ's annual survey of PSOs reflect only those PSOs that responded to the survey. Not all PSOs responded to the survey and not all respondents provided an answer to each survey question.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Patient Safety Organizations at a Glance: 2023

We analyzed data from AHRQ's voluntary annual survey about PSO characteristics and activities. In 2023, there were 108 listed PSOs, and 74 responded to AHRQ's survey (a 69-percent response rate). Of these, 44 said that they worked with hospitals.[36]



Among the 44 PSOs that reported working with hospitals:

Hospital Reach

Nearly **two-thirds** (28 of 44 PSOs) reported that they serve **hospitals in all States.**

PSOs reported working with as many as 946 hospitals and as few as 1 hospital. **At the median, PSOs reported working with 47 hospitals.**[37]

PSO Focus

Most work with any/all clinical disciplines and medical specialties (31 of 44 PSOs). Among the 13 PSOs that work in particular disciplines, they most frequently reported working in surgery (6 of 13 PSOs); neurology (4 of 13 PSOs); and physical medicine and rehabilitation (4 of 13 PSOs).

Patient Safety Activities

About half (23 of 44 PSOs) use a version of AHRQ's Common Formats to receive patient safety reports from hospitals.

The most common resources or services PSOs reported offering were **educational opportunities** (41 of 44 PSOs) and **analysis support for adverse events** (39 of 44 PSOs).

FINDINGS

The PSO program's limited alignment with other efforts hinders opportunities for coordination to improve safety nationwide

The PSO program is one of many patient safety efforts led by HHS agencies, States, payors, accreditors, and other entities. PSOs are involved in some of these efforts, including those led by AHRQ. For example, PSOs share AHRQ's resources (such as patient safety best practices) and participate in the AHRQ-led National Action Alliance for Patient and Workforce Safety. Although hospitals, PSOs, and experts noted some successes in the PSO program, they also explained that the PSO program could be better aligned with other patient safety efforts.

Examples of other patient safety efforts underway at hospitals

Led by HHS: National Action Alliance for Patient and Workforce Safety; CMS's quality-based programs

Led by States: Mandatory patient safety event reporting systems

Led by payors: Quality improvement initiatives at contracted hospitals

Led by accreditors: Patient safety standards that hospitals must meet to become accredited

Led by other entities: Consumer-oriented hospital safety scorecards and rankings; education and training

The PSO program's limited alignment with other patient safety efforts contributes to an increased burden on hospitals. During interviews, we found that the PSO program appeared to compete for hospitals' attention with other mandatory and voluntary efforts, instead of working in tandem to enhance patient safety. Overlap and fragmentation among the efforts of PSOs and other entities can hold providers back from participating robustly with their PSO. Hospitals, patient safety experts, and PSOs described an increased burden on hospitals because the PSO program exists apart from these other efforts. For example, several of the hospitals and PSOs that we interviewed reported that hospitals may need to report an event in different ways to multiple entities, including PSOs. One PSO explained that although its member hospitals submit patient falls data to CMS as a hospital-acquired condition, the data have little value for the PSO's learning purposes. CMS collects the data to adjust Medicare payment based on hospital performance, but the PSO needs different data to help hospitals prevent falls. These measures have different purposes (i.e., accountability versus learning) and therefore may require different data, but this means that hospitals must gather additional data to report to the PSO. In fact, one PSO told us that the reporting burden directly hinders the PSO's ability to collect data from member hospitals.

"We have to [create] an entirely different set of data to really understand how we improve hospital-acquired falls with harm."

A PSO leader describing how varied definitions of patient harm create a reporting burden

We also found that within the PSO program, different PSOs use varying data formats and definitions of patient harm, making it difficult—if not impossible—to aggregate data across PSOs. In AHRQ's 2023 survey of PSOs, about half of PSOs reported using the Common Formats. Even among PSOs that use the Common Formats, they may use different versions of the Common Formats or modified versions developed by individual PSOs. Of the five PSOs we interviewed, four used modified versions of the Common Formats and one PSO did not use the Common Formats at all—meaning that the data collected by these five PSOs may not be comparable. This is notable because the Common Formats were intended to align measures of patient harm. Yet several patient safety experts and advocates told us that national learning around patient safety lags because data are not comparable across organizations. For example, an expert at a patient safety advocacy organization told us that PSOs have different definitions of what constitutes a preventable patient harm event. This hinders analysis and learning from events since PSOs are classifying events in different ways.

The PSO program also appears to be missing opportunities to align with AHRQ's other efforts to improve patient safety. In interviews with AHRQ and patient safety experts, we learned that AHRQ does not fully leverage PSOs to carry out its national research agenda on patient safety. We note that AHRQ uses outreach and surveillance to develop its research agenda, which identifies national priorities for patient safety research, including that funded by AHRQ. AHRQ gathers feedback from PSOs and requests that PSOs communicate to their member hospitals about research opportunities. Beyond this outreach, however, it appears that PSOs are not tapped as possible partners in the research itself. Experts we interviewed told us PSOs' expertise and potentially rich data on patient safety could advance this research. Yet, AHRQ officials said that they were not aware of whether and how PSOs were involved in research funded by HHS, including by AHRQ. This represents a lost opportunity to broaden the reach and impact of PSOs by aligning PSOs more closely with AHRQ's national patient safety research agenda.

Uncertainty in the PSO program's legal protections makes some hospitals hesitant to participate in key aspects of the program

Interviewees expressed lingering uncertainty in the strength of the Patient Safety Act's confidentiality and privilege protections for PSWP, which hampers the PSO program in achieving its full potential in facilitating nationwide learning that can drive improvement in patient safety. Although some hospitals, PSOs, and experts reported that these legal protections have encouraged providers to participate with a PSO, others told us that hospitals remain confused about the extent of these protections. Some hospitals do not trust the privilege protections to prevent PSWP from being used against them in lawsuits or in other adverse actions. These concerns are longstanding: OIG's 2019 report on the PSO program found that uncertainty about the legal protections was challenging for about a quarter of hospitals that worked with a PSO.[38]

Several hospitals and PSOs stated that they had difficulty navigating the Act's legal protections in light of other requirements, such as complying with Medicare and State requirements. They stated that this difficulty contributes to mistrust of the PSO program because they are unsure if complying with the Act's confidentiality protections will put hospitals at odds with other requirements. Hospitals reported that in some cases, State surveyors (acting on behalf of CMS) have requested PSWP, which hospitals believe may contradict the Patient Safety Act. AHRQ officials told us that they work with CMS to clarify PSWP confidentiality protections to surveyors. These clarifications are based on OCR's interpretation of these protections, given that OCR is responsible for enforcing confidentiality protections in the Patient Safety Act. Furthermore, conflicting interpretations of the Patient Safety Act by State courts create confusion about the provisions in the Act. For example, one legal expert who has worked with PSOs told us that some courts rely on a narrower definition of what constitutes PSWP than what the legal expert believes was intended by the Patient Safety Act.

As a result of this uncertainty, hospitals may be hesitant to participate with a PSO or share their data. Some hospitals forgo working with a PSO altogether because they believe they will be exposed to litigation risk if privilege protections are not upheld. PSOs and experts told us that even for hospitals that work with a PSO, mistrust in the privilege protections chills some providers' willingness to report patient safety events to their PSO and learn from those events. It can also discourage hospitals from having their PSOs submit data on their behalf to the NPSD. Specifically, one hospital system and one PSO stated directly that some hospitals question whether the NPSD is truly confidential and fear that HHS will punish them for the patient harm events they share. AHRQ officials acknowledged these concerns and said that they have taken steps to educate providers about how the Act's confidentiality protections extend to data submitted to the NPSD.

Furthermore, experts whom we spoke with at one patient safety advocacy organization contended that the privilege protections are subject to misuse by hospitals. They voiced concerns that hospitals may be misusing the protections as a shield against being held accountable for patient harm caused by breaches in standards of care. For example, a hospital would be misusing the protections if it reported an event to a PSO—thus making it PSWP—solely to prevent the event from being disclosed to patients and families. If these allegations are true, hospitals are acting contrary to the intent of the protections, further eroding the PSO program's promise for national learning to improve patient safety.

The PSO program has not meaningfully engaged patients and families, missing opportunities for further analysis and learning

We found that the PSO program overlooks the role of patients and families, even though their perspectives on harm events are crucial for understanding the extent and impact of patient harm. Experts noted that the Patient Safety Act does not articulate a role for patients and their families in the PSO program, which the experts viewed as a fundamental flaw. They explained that this reflected the patient safety movement at the time the Act was passed in 2005. In the years since, providers and patient safety experts have begun prioritizing input from patients and families.

Despite growing momentum to include patients and families in patient safety efforts, hospitals, PSOs, and experts told us that they were unsure how to involve patients and families in PSOs' work. A key concern is whether the legal protections for PSWP extend to patient-reported safety events. Unsure of the legal protections for patient-submitted reports, PSOs may be hesitant to engage with patients and their families. For example, most of the PSOs we interviewed said that they do not accept patient-submitted reports. Hospitals and PSOs may need guidance on how the PSO program can incorporate patient and family engagement within the framework of the Patient Safety Act.

Finally, AHRQ's existing resources for patient involvement in health care do not appear to be used widely among PSOs. Though the Patient Safety Act does not articulate a role for patients and families, AHRQ offers the Communication and Optimal Resolution (CANDOR) process: a tool to help hospitals communicate with patients and families.[39] Most of the PSOs (four of five) we interviewed told us that they had not integrated CANDOR into their patient safety activities. Only one of the five PSOs that we interviewed told us that it had integrated CANDOR into its patient safety activities. Two PSOs told us directly that they did not use CANDOR or other AHRQ resources to engage patients and families. This is a missed opportunity to leverage existing resources to support patient and family engagement, which research has shown benefits providers' understanding of harm and how to prevent such harm.[40]

The NPSD has not kept pace with newer technology that could support greater participation and trust

The NPSD has not yet delivered on its promise to be a driving force behind nationwide patient safety improvements. Low participation in the NPSD undermines its ability to roll up individual PSO efforts into a single resource that benefits patient safety nationwide, as envisioned in the Patient Safety Act. In 2022, the NPSD received 200,110 event reports, but this likely represents a small fraction of events collected. For example, one PSO told us that it alone collects 500,000 event reports a year. About half of PSOs that reported working with hospitals reported that they used a version of the Common Formats (23 of 44 PSOs), but in 2022 only 3 of the 44 PSOs reported data to the NPSD. Two key drivers of low participation are (1) the lack of a business case for PSOs to submit data to the NPSD, and (2) hospitals' mistrust of the NPSD's data privacy protections.

Submitting data to the NPSD is voluntary, and experts and PSOs described how PSOs lack a strong business case to overcome the financial and operational barriers to submit data. The NPSD accepts data only in the Common Formats, and many PSOs do not use the Common Formats. There are workarounds to using the Common Formats, such as mapping data in other formats to the Common Formats, but prior OIG work found that these methods can be challenging. In addition, experts told us that AHRQ's analysis of NPSD data holds limited value for hospitals and PSOs, which further undermines the business case for PSOs to submit data. Experts told us that the analysis that comes out of the NPSD is mostly high-level trends of the structured data contained in the Common Formats (e.g., the type of event that occurred). This kind of analysis may not be granular enough to provide helpful information needed to improve patient safety. Prior OIG work also highlighted the perceived lack of value among PSOs and hospitals in submitting data to the NPSD.[41]

Even if PSOs are willing to overcome these barriers and submit data to the NPSD on their members' behalf, hospitals may not want this service because of mistrust in the NPSD itself. Interviewees told us that hospitals are concerned that reported events might be shared with other HHS agencies, such as CMS, which could result in punitive action against hospitals. As such, hospitals are reluctant to submit event reports to the NPSD. AHRQ also told us that hospitals have further expressed fears about cybersecurity risks, including risks related to transmitting data from PSOs.

Technology has advanced greatly since the PSO program was created in 2005 and could help the NPSD fulfill its potential as a national resource for learning and improvement. Specifically, newer technologies could help build a business case for PSOs to submit data to the NPSD and increase hospitals' trust in the NPSD. However, experts told us that AHRQ is not fully leveraging these newer technologies.

Below, in Exhibit 1, we describe two technologies that could help the NPSD deliver on its promise as a national system for learning and improvement. On the following page in Exhibit 2, we offer potential ways that these technologies could address barriers to the NPSD.

Exhibit 1: Newer technologies that could support the NPSD

Artificial intelligence (AI)

AI is an umbrella term for using computers to mimic human intelligence, including for data analysis.[42, 43] AI includes methods such as natural language processing, whereby computer models interpret human language contained in unstructured data. In health care, unstructured data include elements such as written narratives in hospitals' internal patient safety incident reports or electronic health records.

Federated data models

A federated data model is a way to analyze data in different formats and from different databases. Instead of transferring data to a central repository for analysis, each organization runs the same query locally.[44] The federated data model then combines the results across the participating organizations. This approach allows entities to retain control of their data and helps them maintain privacy and confidentiality because they do not share the actual data. Furthermore, federated data models can be AI-enabled to drive deeper insight.

Exhibit 2: Barriers facing the NPSD and potential strategies to address them

Barrier	Contributing factors	Potential approaches
PSOs lack a business case to overcome barriers to submitting data to the NPSD	Mapping events to the Common Formats (which is required to submit data to the NPSD) is burdensome.	**AI could automate the process to map data in other formats**, including the Common Formats.[45] For example, these data may exist in hospital electronic health records or a PSO's propriety data formats. **AI could identify patient safety events** in unstructured data (e.g., a narrative incident report in a hospital's internal systems) and map them into the Common Formats. **A federated data model could query PSO data in any format**, eliminating the need to use the Common Formats to aggregate data.
	Analysis from the NPSD holds limited value for hospitals.	AHRQ could glean deeper insights from data it already has by using **AI to analyze unstructured data** contained in the free text fields of the Common Formats. AHRQ could use **an AI-enabled federated data model to incorporate publicly available data from other large patient safety databases** maintained by HHS in its analysis of NPSD data. Doing so can help draw more insightful analysis of patient safety issues from different sources.
Hospitals lack trust in the NPSD	Hospitals are concerned that submitting event-level data to the NPSD may expose them to adverse administrative action from HHS.	**Using a federated data model, hospitals could query their patient safety data and submit the results**, instead of submitting data for individual events.
	Hospitals are concerned about cybersecurity risks of submitting the NPSD.	**A federated data model would allow hospitals to maintain local control over their data**, since the actual data would not be transmitted to the NPSD.

CONCLUSION AND RECOMMENDATIONS

After 20 years, the promise of the PSO program remains unfulfilled. The Patient Safety and Quality Improvement Act of 2005 was landmark legislation intended to advance patient safety nationwide. It created the framework for learning and analysis on a national scale powered by the NPSD and cross-provider collaboration. The program was poised to address entrenched problems in patient safety by allowing PSOs and providers to work together in a confidential and privileged manner. Yet, so far, the PSO program has achieved important successes regionally and within individual health systems but has fallen short in advancing patient safety nationwide.

The root of this lack of progress may be that the PSO program is missing opportunities to more effectively align with the current patient safety movement. The program suffers from siloed data, and definitions of patient harm vary among PSOs. The PSO program has not leveraged technology effectively to address these problems, and hospitals are hesitant to embrace shared learning because they mistrust the Patient Safety Act's legal protections. Furthermore, the PSO program has not defined a role for patients and families, impeding comprehensive learning and understanding of patient harm events.

AHRQ has opportunities to enhance the effectiveness of the PSO program. The agency should bring the PSO program into a new era by using its existing authorities to accelerate nationwide improvement in patient safety.

We recommend that AHRQ:

Increase alignment of the PSO program with other HHS patient safety efforts

AHRQ is leading efforts across HHS to promote patient safety and should increase alignment of the PSO program with those efforts to help improve the program's effectiveness. To better align the PSO program with other patient safety efforts, the agency should:

Integrate PSOs into AHRQ's research priorities. AHRQ should explore ways in which PSOs could have a larger role in supporting AHRQ-funded research to improve the quality and safety of health care. Although PSOs are not contractors or grantees of HHS, AHRQ could more fully exercise the research provision in the Patient Safety Act by encouraging the disclosure of PSWP for research. For example, AHRQ could connect AHRQ-supported researchers with PSOs that have data to support their studies. AHRQ should also continue to highlight opportunities for PSOs to apply for AHRQ research grants or contracts.

Align patient harm definitions across PSOs and providers. AHRQ should standardize harm event definitions to address problems with comparing and aggregating data across providers and PSOs. Because of their broad reach and relationships with hospitals, PSOs are uniquely positioned to assist in a nationwide effort to align patient harm definitions and establish a standard taxonomy of harm events that transcends the Common Formats. As AHRQ works to implement OIG's prior recommendation to align patient safety measures, AHRQ should consult with PSOs in these efforts related to harm event definitions.[46] Specifically PSOs, through their work with member hospitals, could advise AHRQ on how different approaches to defining patient harm and collecting event data may affect the way hospitals and PSOs measure patient harm, and how those data might be aggregated at scale to facilitate national learning. In aligning patient harm definitions, AHRQ should foster a community on patient safety that includes PSOs, patient safety advocates, payors, health care organizations, and other entities.

Promote opportunities to involve patients and families in PSO activities

Given the value of patient and family perspectives in improving patient safety, AHRQ should promote ways for patients and families to participate in PSO activities within the statutory framework of the Patient Safety Act. To do this, AHRQ should consider a new approach for promoting existing resources that could support patient and family involvement. AHRQ has promoted its CANDOR toolkit for facilitating provider disclosure and conflict resolution with patients and families, but hospitals and PSOs remain reluctant to include patients and families in efforts to reduce harm. AHRQ could also consider measuring PSOs' efforts related to patient and family involvement by asking about them in the annual survey of PSO characteristics and activities.

Clarify cybersecurity protections and data use limitations for PSWP submitted to the NPSD

AHRQ should clarify how PSWP is stored and used in the NPSD to address hospitals' concerns that may make them hesitant to submit data to the NPSD. On the basis of interviews with PSOs, hospitals, and experts, some hospitals are concerned that PSWP submitted to the NPSD is not truly confidential or secure. These hospitals are concerned that HHS agencies may have access to PSWP, which could result in negative repercussions (e.g., adverse administrative action by HHS). To address these perceptions, AHRQ should clarify the cybersecurity protections used by its contractor at the PSOPPC, which receives data into the NPSD and renders it nonidentifiable. Furthermore, AHRQ should emphasize to hospitals and PSOs the restrictions on how PSWP submitted to the NPSD may be used. AHRQ could make these clarifications on the PSOPPC website or in data use agreements with PSOs that submit data to the NPSD. Taking these actions would help AHRQ address concerns

and build trust in the NPSD as a key vehicle for national learning and improvement in patient safety.

Take steps to harness technologies and new data sources that could help address barriers facing the NPSD

AHRQ should identify avenues for the PSO program to leverage AI and other technologies that can support patient safety learning. The methods for collecting and analyzing patient safety data laid out in the Patient Safety Act reflect an earlier era when most hospitals did not use electronic health records. By making use of newer technologies, the PSO program could increase the number of patient safety events that PSOs submit and ease the reporting burden on providers and PSOs alike. In addition, the NPSD could receive more data if AHRQ used newer technologies to reduce barriers to submission, including those related to the Common Formats. Further, experts explained that unstructured data, such as electronic health records, have untapped potential for identifying patient safety events and contributing factors. We note that prior OIG work released in 2019 urged AHRQ to explore using advanced technologies to accept and analyze such data.[47] Current AI tools now appear to hold the key to analyzing unstructured data at scale.

Furthermore, technologies such as AI-enabled federated data models could enable AHRQ to explore tapping other large publicly available HHS patient safety databases alongside the NPSD to draw deeper insights on patient harm. For example, FDA's Manufacturer and User Facility Device Experience and Adverse Event Reporting System and HHS's Quality and Safety Review System collectively contain millions of records. AI-enabled federated learning that draws on the NPSD and these or other data sources could yield national learning and improvement in patient safety on the scale envisioned by the Patient Safety Act. Importantly, with proper governance and controls, it could do so while safeguarding the privacy and confidentiality of each data source.

AGENCY COMMENTS AND OIG RESPONSE

AHRQ concurred with all four of our recommendations.

In response to our first recommendation to increase alignment of the PSO program with other patient safety efforts, AHRQ outlined plans to integrate PSOs into ongoing and future work to advance research and align patient safety event measurement. To integrate PSOs with the agency's research priorities, AHRQ said, it will disseminate further information about the disclosure of PSWP for research and will continue efforts to inform PSOs of future AHRQ opportunities for research grants and contracts. To illustrate how it will align patient harm definitions across PSOs and with other HHS safety efforts, AHRQ reiterated its plans to participate in the National Quality Forum's "Focus on HARM" initiative, a public-private partnership tasked with updating the Serious Reportable Events list to reflect current harm events and harmonize reporting of such events. Upon completion of this initiative, AHRQ said, it plans to review the Common Formats to determine whether updates are needed. AHRQ stated that there will be opportunities for PSOs to contribute to these initiatives and provide feedback.

Although it concurred with this recommendation, AHRQ disagreed with our characterization that the PSO program had limited alignment with other national patient safety efforts. AHRQ pointed to ways that the PSO program is represented in AHRQ's other patient safety efforts, such as PSOs' involvement in the National Steering Committee for Patient Safety and in developing and implementing CMS's Patient Safety Structural Measure for hospital reporting. OIG appreciates AHRQ's reference to these ongoing and important efforts to align the PSO program with nationwide patient safety efforts, and to its planned efforts summarized above. Our findings—informed by interviews with PSOs, hospitals, and patient safety experts—demonstrate that additional action toward alignment is warranted.

In response to our second recommendation to promote opportunities to involve patients and families in PSO activities, AHRQ stated that it will intensify its efforts to engage with PSOs on opportunities to involve patients and families, including sharing agency tools such as CANDOR. AHRQ said that it will explore collecting information about how PSOs engage patients and families through new questions on its annual survey to PSOs (known as the PSO Profile Form). AHRQ stated that its ability to add new questions is contingent on approval from the Office of Management and Budget. To explore opportunities for patient, family, and caregiver involvement in the PSO program, AHRQ said, it plans to meet with stakeholders and consider whether to solicit broader public input, such as with a Request for Information.

In response to our third recommendation to clarify cybersecurity protections and data use limitations for PSWP submitted to the NPSD, AHRQ stated that it will add additional clarification to the PSOPPC website regarding security protections and data use limitations. AHRQ said it will review the data use agreements between

PSOs, or their vendors, and the PSOPPC to assess whether further clarification is needed. AHRQ committed to completing these activities by September 2026 to coincide with an ongoing update of the PSOPPC website.

In response to our fourth recommendation to take steps to harness technologies and new data sources that could help address barriers facing the NPSD, AHRQ stated that it has ongoing activities to this end. AHRQ noted that funds were approved in fiscal year 2024 to enhance the information technology infrastructure of the PSOPPC to support additional methods of data collection in the NPSD. This effort includes mapping the Common Formats to the United States Core Data for Interoperability (USCDI) and USCDI+ standards. AHRQ stated that this will make it easier for providers to report in the Common Formats without having to map data in other formats. AHRQ also provided a list of additional activities that it plans to complete by September 2026 to support the NPSD's ability to use technology to drive patient safety insights.

AHRQ agreed that connecting the NPSD to other large publicly available HHS databases could provide further patient safety insights, but stated that, at the time of our report, it does not have the resources to support this kind of federated data model. OIG acknowledges that establishing a federated data model may require considerable resources, and we encourage AHRQ to explore the feasibility of this effort and to work with HHS partners as appropriate.

OIG supports AHRQ's actions and believes that these ongoing and planned efforts will help address the PSO program's challenges and advance patient safety. For the full text of AHRQ's comments, see Appendix B.

APPENDICES

Appendix A: Patient Safety Activities

To be listed as a PSO, an organization must certify that it can perform the following activities:

1. Efforts to improve patient safety and the quality of health care delivery.
2. The collection and analysis of patient safety work product.
3. The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.
4. The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.
5. The maintenance of procedures to preserve confidentiality with respect to patient safety work product.
6. The provision of appropriate security measures with respect to patient safety work product.
7. The utilization of qualified staff.
8. Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.[48]

Appendix B: Agency Comments

Following this page are the official comments from AHRQ.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Date: August 13, 2025

To: Ann Maxwell
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General (OIG)

From: Roger D. Klein, MD, JD
Director, Agency for Healthcare Research and Quality (AHRQ)

Subject: AHRQ Comments on OIG Draft Issue Brief, *The Patient Safety Organization Program: Key Barriers Impeding Nationwide Progress in Reducing Patient Harm in Hospitals,* OEI-01-24-00150

Thank you for the opportunity to provide comment on this draft issue brief and for OIG's ongoing interest in maximizing the success of the Patient Safety Organization (PSO) program.

More progress must be made to realize a future with "safe care everywhere and zero preventable harm for all," the vision of the AHRQ-led National Action Alliance for Patient and Workforce Safety (NAA). Nevertheless, AHRQ is encouraged by recent advances in patient safety since the COVID-19 pandemic. While this draft issue brief notes OIG's findings of patient harm for hospitalized Medicare patients from 2008 and 2018, more recent data from a joint project by AHRQ and the Centers for Medicare & Medicaid Services (CMS) shows an approximately 25% decline from 2021 to 2023 in the percentage of Medicare patients experiencing adverse events during their hospitalization.[1] With ongoing support from public and private partners, including the PSOs, the NAA's goal of reducing harm by 50% by 2026 from the peak of the pandemic is within reach.

PSOs play a pivotal role in supporting healthcare providers in improving patient safety and quality. As OIG found in its 2019 report on the PSO program, nearly all general acute-care hospitals that work with a PSO found it valuable, and 80% of the hospitals that work with a PSO reported that the PSO's feedback helped prevent future patient safety events.[2] As a testament to the value of PSOs, since the OIG's 2019 report, the PSO program has grown significantly, with 123 PSOs currently listed by AHRQ – a more than 30% increase from the number of PSOs listed in 2019.

And while OIG's draft issue brief focuses on hospital engagement with PSOs, PSOs work with providers across the healthcare continuum. In the 2024 voluntary survey of PSOs, 59

[1] National Action Alliance for Patient and Workforce Safety. Agency for Healthcare Research and Quality, Rockville, MD. https://datatools.ahrq.gov/action-alliance.

[2] *Patient Safety Organizations: Hospital Participation, Value, and Challenges*, OEI-01-17-00420, available at: https://oig.hhs.gov/reports/all/2019/patient-safety-organizations-hospital-participation-value-and-challenges/.

PSOs responded about the types of providers with whom they work. Hospitals accounted for only 13% of the 29,920 provider types identified by PSOs in this survey; the vast majority of the providers were other types such as licensed practitioner groups, urgent care facilities, specialized treatment facilities, long-term care, and retail pharmacies. As such, much of the impact of PSOs on improving patient safety and healthcare quality is overlooked in this draft issue brief, as it is outside of OIG's defined scope. AHRQ is appreciative of the tens of thousands of healthcare providers who have chosen to work with one or more PSOs, as well as the past and present PSOs, who have prioritized enhancing patient safety and improving health care quality across the United States. We look forward to implementing OIG's recommendations to support the PSOs in expanding the impact of their ongoing work.

AHRQ's specific responses to OIG's recommendations appear below. As noted in the draft issue brief, in March 2025, HHS announced that AHRQ will become part of a new HHS Office of Strategy. AHRQ will inform OIG if this restructuring impacts our response to the below recommendations.

OIG Recommendation: Increase alignment of the PSO program with other HHS patient safety efforts

AHRQ Response: AHRQ concurs with this recommendation and will work to further foster the existing close alignment of the PSO program with other HHS patient safety efforts. AHRQ disagrees with characterizing the alignment of the PSO program with other national patient safety efforts as "limited." For example, the PSO program is well represented in the National Steering Committee for Patient Safety, convened by the Institute for Healthcare Improvement, which created the National Action Plan to Advance Patient Safety. The National Steering Committee includes champions of the PSO community in its leadership and additional member representation from PSOs as well as from AHRQ's Center for Quality Improvement and Patient Safety (where the PSO program resides). Over the years, AHRQ has shared the work of the National Steering Committee with the broader PSO community and supported PSO implementation of the national action plan, including through sessions at AHRQ's annual PSO meeting. As another example, the PSO community has been actively engaged in the CMS' Patient Safety Structural Measure (PSSM) from development through implementation. The PSSM was informed by the National Action Plan to Advance Patient Safety[3], and CMS worked closely with AHRQ in developing several aspects of the measure. PSO community stakeholders provided public comment on the draft measure, which resulted in changes to the language about working with a PSO in the final version of the measure.[4] PSOs are key partners to many hospitals in implementing the five domains of the PSSM, and AHRQ has supported these efforts, including through highlighting examples of such work during presentations at the annual PSO meeting.

As to the portion of the recommendation regarding integrating PSOs into AHRQ's research priorities, AHRQ will seek to provide further information about the disclosure of patient safety work product (PSWP) for research on the PSO program website. AHRQ's ability to provide such further information is dependent upon the availability of the Office for Civil

[3] 89 Fed. Reg. 69457 (Aug. 28, 2024).
[4] 89 Fed. Reg. 69478 (Aug. 28, 2024).

Rights to coordinate such information. AHRQ will also continue to inform PSOs of future AHRQ opportunities for research grants or contracts.

Regarding the portion of the recommendation to align patient harm definitions, AHRQ reiterates our plans to partake in the activities described in response to OIG's recent draft report, *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer* (OEI-06-18-0041). This includes AHRQ's continued participation in the National Quality Forum's "Focus on HARM" initiative, a public-private partnership, which launched to update the Serious Reportable Events (SRE) list to reflect current healthcare delivery harm events and harmonize reporting of such events.[5] Upon completion of the "Focus on Harm" initiative, AHRQ will review the Common Formats to determine whether updates are needed. Opportunities to contribute to and provide feedback on these activities will continue to be shared through the Patient Safety Organization (PSO) network.

OIG Recommendation: Promote opportunities to involve patients and families in PSO activities

AHRQ Response: AHRQ concurs with this recommendation and will redouble our efforts to engage with the PSOs on opportunities to involve patients and families. As an example of prior activities we have led in this domain, we hosted a discussion on communication and resolution programs (such as CANDOR), during our 2024 annual PSO meeting, emphasizing how such programs can align with PSO activities. This session included a multi-disciplinary panel to provide the perspectives of legal, risk management, PSOs, and patient and families, among others. AHRQ will also continue to share with PSOs existing AHRQ tools to help prioritize concerns and maximize interactions between providers, patients, and families, such as providing further information on these tools during an upcoming 2025 PSO quarterly call. In addition, AHRQ will explore collecting information on how PSOs engage patients and families in the annual PSO Profile Form that we ask PSOs to complete. Adding such questions to the form will likely require approval from the Office of Management and Budget, but pending such approval, AHRQ will work towards including these data elements in the 2025 profile form. As noted in this draft issue brief, the PSO Program's statutory authority does not set forth a role for patients and their families or other caregivers. Thus, AHRQ will plan to meet with relevant stakeholders, such as patient and family advocates in the area of patient safety, to explore this opportunity further. After such initial discussions, AHRQ will consider whether broader feedback is needed, and, if so, will explore additional mechanisms for public input, such as a Request for Information published in the Federal Register.

OIG Recommendation: Clarify cybersecurity protections and data use limitations for PSWP submitted to the NPSD

[5] National Quality Forum. (2024, Apr 04). *NQF to Update and Harmonize Serious Adverse Event Reporting Criteria Essential to Protect Patients From Preventable Harm.* https://www.qualityforum.org/News_And_Resources/Press_Releases/2024/NQF_to_Update_and_Harmonize_Serious_Adverse_Event_Reporting_Criteria_Essential_to_Protect_Patients_From_Preventable_Harm.aspx

AHRQ Response: AHRQ concurs with this recommendation and will add additional clarification to the PSO Privacy Protection Center (PSOPPC)'s website regarding security protections and data use limitations. While the data use agreements between PSOs, or their vendors, and the PSOPPC already address data use limitations, AHRQ will review the agreement along with the PSOPPC to see if any further clarifications would be appropriate. AHRQ aims to complete these activities by September 2026, to coincide with an ongoing project to refresh the PSOPPC website.

OIG Recommendation: Take steps to harness technologies and new data sources that could help address barriers facing the NPSD

AHRQ Response: AHRQ concurs with this recommendation and will continue its current activities to leverage new technologies to encourage data submission to the NPSD. AHRQ agrees that technology has significantly advanced since the inception of the program such that methods of data transfer between the PSOs and the PSOPPC that are less burdensome for the PSOs are feasible, subject to availability of resources to develop the infrastructure and related resources. In 2022, the PSO program prepared a Nonrecurring Expenses Fund request to enhance the information technology infrastructure of the PSOPPC to support additional methods of data collection, which was approved for Fiscal Year 2024. Since September 2024, AHRQ has been working closely with its contractor that operates the PSOPPC to complete supporting activities, including mapping the Common Formats to the United States Core Data for Interoperability (USCDI) and USCDI+ standards. Aligning the Common Formats with the USCDI data elements will make it easier for providers to report in the Common Formats without having to "map" data from the electronic health record to different Common Formats data elements.

Additional activities currently in progress and scheduled to be completed by September 2026 include:

- Creating a Patient Safety Data Interoperability hub on the PSOPPC website
- Assessing the ability of PSOs to utilize Fast Healthcare Interoperability Resources (FHIR) standards to submit data to the PSOPPC, including through completing a Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis of PSOs readiness to utilize FHIR standards and convening a FHIR workgroup with the PSO and software developer community.
- Creating FHIR profiles specific to patient safety data
- Developing SMART on FHIR and restful application programming interfaces capable of transmitting patient safety data
- Updating the PSOPPC import processor to accept data aligning with FHIR and USCDI standards
- Conducting pilot testing on PSOs submitting data to the PSOPPC using FHIR technology

AHRQ agrees that connecting the NPSD with other large publicly-available HHS databases could provide further patient safety insights. However, the PSO program is not currently resourced to support such a federated data model. If additional resources were to become available, AHRQ would reconsider if exploration of such activities were feasible.

We look forward to working with you on the proposed activities described above. Please feel free to contact Andrea Timashenka, JD, PSO Division Director, Center for Quality Improvement and Patient Safety at AHRQ, with any questions.

Roger D. Klein, MD, JD

ENDNOTES

[1] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-09-00090), Nov. 2010; OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022; OIG, *Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-14-00530), Nov. 2018; OIG, *Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-14-00110), Jul. 2016; OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries* (OEI-06-11-00370), Feb. 2014.

[2] OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022; OIG, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm* (OEI-06-09-00091), Jan. 5, 2012.

[3] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-09-00090), Nov. 2010.

[4] OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022.

[5] AHRQ, *About the PSO Program*. Accessed on May 30, 2025.

[6] OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022; OIG, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm* (OEI-06-09-00091), Jan. 5, 2012.

[7] Pub. L. No. 109-41 (July 29, 2005), adding sections 921 through 926 to the Public Health Service Act (42 U.S.C. §§ 299b-21 to 299 b-26).

[8] Kohn, Linda T., et al., *To Err Is Human: Building a Safer Health System, A Report of the Committee on Quality of Health Care in America*, Institute of Medicine, National Academies Press, 2000.

[9] 73 Fed. Reg. 70732 (Nov. 21, 2008).

[10] 42 U.S.C. § 299b-22.

[11] 73 Fed. Reg. 70732 (Nov. 21, 2008).

[12] 73 Fed. Reg. 70732 (Nov. 21, 2008), codified at 42 CFR §§ 3.10 - 3.552.

[13] AHRQ, *Improving Patient Safety by Engaging Patients and Families*. Accessed on Apr. 3, 2025.

[14] National Steering Committee for Patient Safety, *Safer Together: A National Action Plan to Advance Patient Safety*, Institute of Medicine, 2020.

[15] AHRQ, *Communication and Optimal Resolution (CANDOR)*. Accessed on Mar. 6, 2025.

[16] 42 U.S.C. §§ 299b-21 and 299b-24.

[17] In addition to the exclusions listed in the text, a PSO may not be an entity that operates a Federal, State, local, or Tribal patient safety reporting system to which health care providers (other than members of the entity's workforce or health care providers holding privileges with the entity) are required to report information by law or regulation. See 42 CFR 3.102(a)(2)(ii)(D).

[18] Although PSOs are not Federal contractors, Federal agencies may choose to set up their own PSOs as separate legal entities. See 42 CFR § 3.20. OIG is not aware of any PSOs that are a component of a Federal agency.

[19] 42 U.S.C. §§ 299b-21(5) and 299b-24(a).

[20] 42 U.S.C. § 299b-24(a)(2).

[21] AHRQ, *Stories From the Field*. Accessed on Apr. 17, 2025.

[22] Levy, Fiona H., et al., "The Child Health PSO at 10 Years: An Emerging Learning Network," *Pediatric Quality & Safety*, Aug. 2021.

[23] A literature review conducted by the National Institutes of Health (NIH) on behalf of OIG yielded few results on academic articles and studies on the value of the PSO program.

[24] 42 U.S.C. § 299b-21. PSWP also includes data and analyses developed by a PSO for the conduct of patient safety activities.

[25] 42 U.S.C. § 299b-22.

[26] 71 Fed. Reg. 28701 (May 17, 2006).

[27] 42 U.S.C. § 299b-23.

[28] 42 U.S.C. § 299b-23(c).

[29] AHRQ, *What is the Network of Patient Safety Databases?* Accessed on Feb. 15, 2024.

[30] AHRQ, *Network of Patient Safety Databases Chartbook, 2023*, Sep. 2023. Accessed on Mar. 6, 2025.

[31] HHS, *HHS Announces Transformation to Make America Healthy Again*, Mar. 27, 2025. Accessed on Apr. 14, 2025.

[32] OIG, *Patient Safety Organizations: Hospital Participation, Value, and Challenges* (OEI-01-17-00420), Sep. 25, 2019.

[33] AHRQ, *NPSD Data Spotlight: Patient Safety and COVID-19: A Qualitative Analysis of Concerns During the Public Health Emergency*, Nov. 2021. Accessed on Mar. 6, 2025.

[34] OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022.

[35] OIG, *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer* (OEI-06-18-00401), Jul. 23, 2025.

[36] Not all PSOs that responded to the survey gave an answer for each question. Thus, some data are not generalizable to all PSOs.

[37] The interquartile range, which represents the spread of the middle half of PSOs, is about 58 hospitals. The 25th percentile is 20 hospitals and the 75th percentile is about 78 hospitals.

[38] OIG, *Patient Safety Organizations: Hospital Participation, Value, and Challenges* (OEI-01-17-00420), Sep. 25, 2019.

[39] AHRQ, *Communication and Optimal Resolution (CANDOR)*. Accessed on Mar. 6, 2025.

[40] AHRQ, *Improving Patient Safety by Engaging Patients and Families*. Accessed on Apr. 3, 2025.

[41] OIG, *Patient Safety Organizations: Hospital Participation, Value, and Challenges* (OEI-01-17-00420), Sep. 25, 2019.

[42] Tighe, Patrick, et al., *Artificial Intelligence and Patient Safety: Promise and Challenges*, PSNet, Mar. 27, 2024.

[43] National Academy of Medicine, *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril*, 2022.

[44] van Genderen, Michel E., et al., Federated Data Access and Federated Learning: Improved Data Sharing, AI Model Development, and Learning in Intensive Care," *Intensive Care Medicine*, Apr. 18, 2024.

[45] Johnson, Steven G., et al., "Machine Learned Mapping of Local EHR Flowsheet Data to Standard Information Models using Topic Model Filtering," *AMIA Annual Symposium Proceedings*, Mar. 4, 2020.

[46] OIG, *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer* (OEI-06-18-00401), Jul. 23, 2025.

[47] OIG, *Patient Safety Organizations: Hospital Participation, Value, and Challenges* (OEI-01-17-00420), Sep. 25, 2019.

[48] 42 U.S.C. §§ 299b-21(5) and 299b-24(a).

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