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Patient Safety Organizations: Hospital Participation, Value, and Challenges

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Patient Safety Organizations: Hospital Participation, Value, and Challenges

The Agency for Healthcare Research and Quality's (AHRQ's) voluntary Patient Safety Organization (PSO) program is the first and only nationwide program that offers legal protections for providers to disclose and learn from patient safety events. An organization must meet AHRQ's criteria to be federally listed as a PSO. The program is also the only program to establish a Network of Patient Safety Databases (NPSD) to enable learning on a national scale about the causes of such events.

Key Takeaway
Many hospitals that participate in the Patient Safety Organization program find that it has improved patient safety. However, challenges have slowed progress toward a national system of learning to improve patient safety.

What OIG Found

Over half of general acute-care hospitals work with a PSO, and nearly all of them find it valuable. Among hospitals that work with a PSO, 80 percent find that the PSO's feedback and analysis on patient safety events have helped prevent future patient safety events.

However, the PSO program faces challenges. Hospitals that do not participate do not perceive the PSO program to be distinct from other patient safety efforts. Nearly all of these hospitals cited redundancy relative to other patient safety efforts as a reason they do not participate. Uncertainty over the program's legal protections and determining what information is protected can be challenging for hospitals. This may discourage them from disclosing data to their respective PSOs or participating at all. Although the Common Formats (standard methods for reporting patient safety data) enable AHRQ to aggregate and analyze data, requiring them for the NPSD may slow its progress. Forty-two percent (31 of 74) of PSOs cannot contribute to the NPSD because they do not use the Common Formats. Challenges with the Common Formats reflect the limits of using a standardized approach to capturing patient safety data. Finally, AHRQ provides technical assistance that PSOs find helpful, but its guidance falls short of meeting PSOs' needs.

What OIG Recommends

AHRQ should do more to support and promote the PSO program. Specifically, the Office of Inspector General recommends that AHRQ (1) develop and execute a communications strategy to increase nonparticipating hospitals' awareness of the PSO program and the program's value to participants; (2) take steps to encourage PSOs to participate in the NPSD, including accepting data into the NPSD in other formats in addition to the Common Formats; and (3) update guidance for PSOs on processes for listing PSOs. AHRQ concurred with our first and third recommendations and partially concurred with our second recommendation.

Full report can be found at oig.hhs.gov/oei/reports/oei-01-17-00420.asp

Why OIG Did This Review

Researchers have estimated that over 200,000 people die each year because of medical errors in hospitals. Learning from those and other, nonfatal events to improve patient safety is the goal of the PSO program. Hospitals' descriptions of their experiences with the program provide insight into the program's progress toward facilitating national learning from patient safety events. This review is the first to explore the extent to which hospitals participate in the PSO program and their perspectives on its values and challenges. It builds on previous Office of Inspector General work from 2010 that found 27 percent of hospitalized Medicare beneficiaries experienced harm because of medical care. OIG recommended, among other things, that AHRQ encourage hospitals to participate in the PSO program.

How OIG Did This Review

We selected a random sample of 600 general acute-care hospitals to survey and achieved a 79-percent response rate. We asked them detailed questions about their experiences in working with federally listed PSOs and their perceived value of the program. We also surveyed all federally listed PSOs, achieving a 90-percent response rate. We asked them detailed questions about their experiences in working with hospitals and with AHRQ. Finally, we interviewed AHRQ staff and reviewed data on AHRQ's oversight of the program from 2009 through 2017.

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BACKGROUND

Objectives

1. To determine the extent to which hospitals participate in the PSO program.
2. To describe hospital perspectives on the value of the PSO program.
3. To describe challenges to the PSO program.
4. To assess the Agency for Healthcare Research and Quality's oversight of the PSO program.

Researchers have estimated that over 200,000 people die each year because of medical errors in hospitals.[1] The aim of the Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act, or the Act) is to improve patient safety by encouraging learning from these and other, nonfatal events.[2] The Act created the Patient Safety Organization (PSO) program and established PSOs to collect, aggregate, and analyze patient safety information submitted by providers. All aspects of participation in the PSO program are voluntary.[3] To address providers' fears that such information would be used against them, the Act also established the first and only comprehensive, nationwide confidentiality and privilege protections (hereinafter, legal protections) for certain patient safety information that providers submit to PSOs.[4] The Act also requires a national Network of Patient Safety Databases (NPSD) to aggregate and analyze nonidentifiable patient safety data and make it available for researchers.[5] The Institute of Medicine—now the Health and Medicine Division of the National Academies—called for such a reporting and learning system in its landmark 1999 report *To Err Is Human: Building a Safer Health System*.[6]

In 2010, the Office of Inspector General (OIG) found that 27 percent of hospitalized Medicare beneficiaries experienced harm because of medical care.[7] In that report we recommended that the Agency for Healthcare Research and Quality (AHRQ) should, among other activities, enhance its efforts to identify adverse events, in part by continuing to encourage hospitals to participate in the Patient Safety Organization (PSO) program.

This study examines the extent to which hospitals have participated in and received value from the PSO program; identifies challenges associated with it; and assesses AHRQ's oversight of the program. It contributes to OIG's body of work on patient safety.

The PSO Program

In 2006, the Secretary of Health and Human Services delegated most authorities under the Patient Safety Act to AHRQ. The Secretary delegated the responsibility for interpreting and enforcing the legal protections of the

Patient Safety Act to the Office for Civil Rights (OCR).[8] In 2008, the Department of Health and Human Services (HHS) published a final rule implementing the Act.[9]

Patient Safety Organizations

Central to the PSO program are organizations that meet AHRQ's requirements to be federally listed as PSOs. PSOs are private organizations—which may be consulting firms, health care providers, or other entities—that serve as patient safety experts for health care providers that choose to work with them (hereinafter referred to as PSOs' members).[10,] PSOs may be nonprofit or for-profit. A PSO's members may also choose to disclose information about patient safety events and other patient safety information to the PSO.

A PSO is required to perform certain patient safety activities to be federally listed as a PSO. These activities include, but are not limited to, efforts to improve patient safety and the quality of health care delivery; the collection and analysis of Patient Safety Work Product (PSWP), which we discuss in more detail below; and procedures to preserve the confidentiality of PSWP.

PSOs may perform these activities in various ways, such as analyzing data to identify the causes of patient safety events; developing recommendations to prevent future events and improve patient safety; and facilitating the sharing of best practices among providers to enhance learning.[11] As of July 2019, 83 organizations were listed with AHRQ as federally listed PSOs.

Patient Safety Work Product and Its Legal Protections

The Patient Safety Act established legal protections for certain information—when it meets the definition of PSWP—that providers disclose to PSOs.[12] In general, the Act defines PSWP as including any data, reports, records, memoranda, analysis, or statements that are assembled or developed by a provider for reporting to a PSO and are reported to a PSO; or are developed by a PSO for conducting patient safety activities.[13] The Act also excludes medical records, among other records, from the definition of PSWP.

PSWP is not generally subject to subpoena or discovery in criminal, civil, or administrative proceedings, including disciplinary action against a provider.[14, 15] Additionally, PSWP is not subject to disclosure under the Freedom of Information Act.[16] According to HHS, these protections alleviate "concerns about such information being used against a provider, such as in litigation."[17]

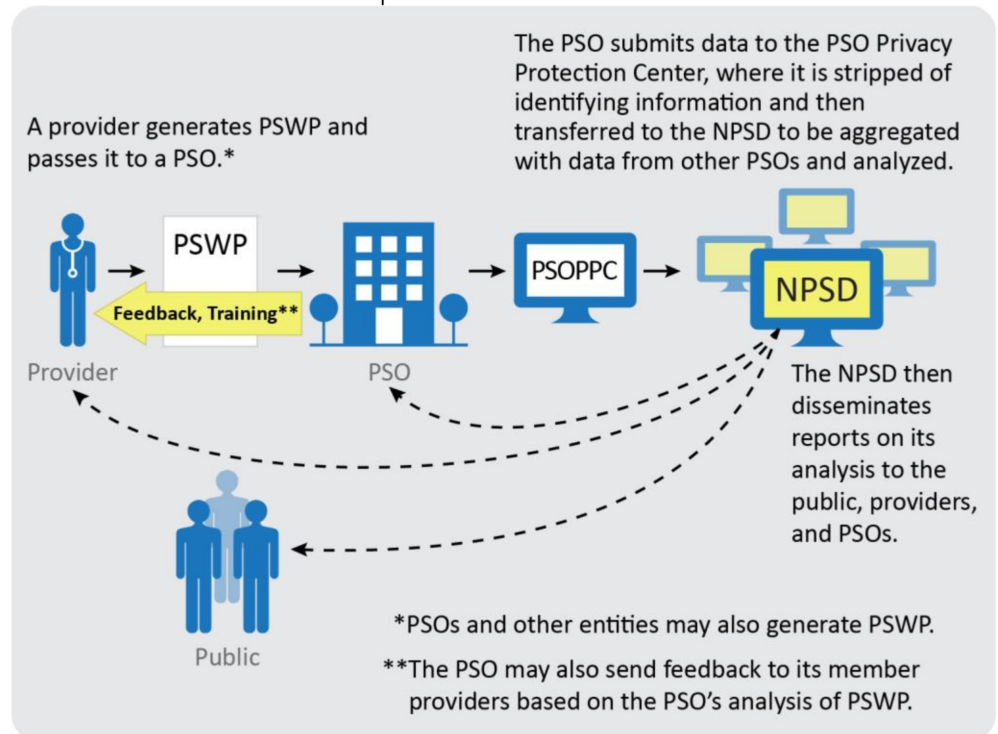
Network of Patient Safety Databases

The Patient Safety Act directed the Secretary of HHS to develop the NPSD to enable national learning about patient safety events. According to the Act, the NPSD should have the capacity to accept, aggregate, and analyze other entities.[18] AHRQ and others are to use the NPSD data to analyze national and regional statistics, including trends and patterns of health care

errors.[19] AHRQ is to report on the findings from this analysis.[20] An intermediary known as the PSO Privacy Protection Center (PSOPPC) renders data nonidentifiable before it reaches the NPSD (see Exhibit 1). A contractor operates both the PSOPPC and the NPSD for AHRQ.

In a 2010 report, the Government Accountability Office found that AHRQ was in the process of developing the NPSD and expected it to be ready to receive data from hospitals by February 2011.[21] The PSOPPC, which renders data nonidentifiable, was ready to receive data in 2012. In 2017, AHRQ told us that although some PSOs had submitted data, the PSOPPC had not yet released data to the NPSD because its process for rendering data nonidentifiable limited the utility of the data. Furthermore, AHRQ also noted that the process may limit the quantity of data that could be made available to the public. The PSOPPC tested methods for preparing data for the NPSD, and AHRQ launched the public-facing NPSD website on June 21, 2019.

Exhibit 1. PSWP flows from providers and PSOs to the NPSD.



Common Formats

As permitted by the Patient Safety Act, AHRQ developed common definitions and formats—known as the Common Formats—for reporting patient safety event data. It did so in collaboration with the National Quality Forum and with input from stakeholders including PSOs and providers. The Common Formats make it possible for AHRQ and others to aggregate and analyze patient safety event data. As of 2019, AHRQ has released Common Formats for reporting events that occur in three settings of care: acute-care hospitals, community pharmacies, and skilled nursing facilities. AHRQ continues to develop new versions of the Common Formats.

PSOs are not required to use the Common Formats. However, although PSOs may collect data in any standardized format that permits valid comparisons of similar cases among similar providers, the NPSD accepts only data in the Common Formats. Federally listed PSOs must use either the Common Formats or an alternative system of formats and definitions, or provide a clear explanation why it is not practical or appropriate to do either.[22]

AHRQ Oversight of the PSO Program

PSO Listing and Certification

The Patient Safety Act directed the Secretary of HHS to compile and maintain a list of PSOs. Accordingly, an entity wishing to be listed as a PSO must submit a certification to AHRQ attesting that it has policies and procedures in place to perform the patient safety activities described in the Act. It must also attest to meeting additional criteria described in the Act, which include having a qualified workforce, not being a health insurer, and having at least two bona fide contracts with providers every 2 years.[23] AHRQ reviews and verifies the certification and ensures that the entity understands the implications of becoming a PSO. If AHRQ accepts the entity's certifications, AHRQ will list the entity as a PSO.[24]

After its initial certification, a PSO must recertify with AHRQ every 3 years.[25] AHRQ calls its review of a PSO's recertification a continued listing review (see Exhibit 2 on the next page). AHRQ may also conduct an announced or unannounced compliance review of a PSO to verify compliance with the Act and the final rule that implemented the Act. If AHRQ finds that a PSO is not in compliance, AHRQ may file a notice of preliminary finding of deficiency with the PSO, requiring it to remedy the specified deficiencies.

Exhibit 2. AHRQ performed its oversight responsibilities as set forth in the Patient Safety Act.[26]

AHRQ Oversight Activity

From 2008 through 2017, AHRQ:

Approved	Approved	Conducted	Delisted
164	**140**	**13**	**79**
Initial Listings	**Continued Listings**	**Compliance Reviews**	**PSOs**
AHRQ listed an average of 16 new PSOs per year, with a range of 5 to 36 PSOs per year	AHRQ approved an average of 20 continued listings each year from 2011 to 2017, with a range of 14 to 29 continued listings per year	3 compliance reviews resulted in corrective action and 2 resulted in expedited revocation	**69** PSOs voluntarily relinquished their respective listings, **5** listings expired, and **5** PSOs were delisted for cause

Source: OIG analysis of AHRQ listing data, 2018.

AHRQ is also responsible for delisting PSOs that do not meet requirements of the Act. Delisting refers to the loss of a PSO's federally listed status, and AHRQ may delist a PSO for three reasons: the PSO voluntarily relinquishes its status as a PSO; the PSO's listing expires; or AHRQ revokes the PSO's listing for cause. AHRQ may revoke a PSO's listing for cause if the PSO fails to correct a deficiency.[27]

Technical Assistance

The Patient Safety Act authorized the Secretary of HHS to "provide technical assistance to [PSOs], including convening annual meetings for [PSOs] to discuss methodology, communication, data collection, or privacy concerns."[28] Accordingly, AHRQ hosts an annual meeting for PSOs. Topics at the 2018 meeting included sessions in which PSOs shared successful practices and discussions on how AHRQ could improve and support the PSO program. AHRQ also provides technical assistance by responding to inquiries from PSOs and making resources available on its website.[29]

Litigation Regarding the Act's Legal Protections for PSWP

The legal protections for PSWP have been tested through the courts, with varied outcomes. For example, in 2012, an Illinois appellate court affirmed a trial court's decision that pharmacy incident reports constituted PSWP and were protected under the Act.[30] However, since this case, some State courts have found that the Act does not protect certain information. In 2014, the Kentucky Supreme Court held that adverse event reports created to comply with State laws are not protected.[31] The Florida Supreme Court came to a similar conclusion in 2017.[32] The U.S. Supreme Court denied petitions to review both the Kentucky and Florida cases.[33, 34]

In 2016, the Kentucky Supreme Court heard another case on the scope of the privileges provided by the Act. It ruled that documents collected, maintained, or developed for the sole purpose of reporting to a PSO are privileged. The Court also clarified that providers may store information in their respective patient-safety evaluation systems but that doing so does not relieve providers from their State and Federal reporting requirements.[35]

Such cases spurred debate among stakeholders over what constitutes PSWP. In 2016, HHS issued guidance to clarify the definition, stating that "information prepared for purposes other than reporting to a PSO is not PSWP."[36] HHS's guidance did not settle the uncertainty over PSWP for some. Providers may be reluctant to disclose data that they are uncertain will meet the definition of PSWP and be protected in the State and Federal courts.

Methodology

Scope

This report is based on the results of surveys that we sent to all PSOs listed with AHRQ as of April 2018 and to a nationally representative sample of general acute-care hospitals that participated with Medicare as of February 2018. Our findings on the PSOs' characteristics, services, and their interactions with AHRQ encompass all PSOs that responded to our survey. Our findings on PSOs' experiences working with hospitals reflect only those PSOs that identified themselves as working with hospitals. Our findings on AHRQ's oversight considered the agency's activities from 2008 through 2017.

Data Sources and Analysis

To conduct this study, we relied on multiple data sources.

PSO Survey

We sent an electronic survey to all 82 PSOs listed on the AHRQ website at the time of our survey. PSOs could respond to the survey from May 1, 2018, through June 15, 2018; 74 PSOs responded, a 90-percent response rate. The survey included questions related to PSO characteristics, services PSOs offer, and challenges PSOs face.

Hospital Survey

We selected a nationally representative, simple random sample of 600 general acute-care hospitals to ask about their experiences with federally listed PSOs. We selected the random sample from among all 3,400 general acute-care hospitals that participated in Medicare in 2018. Of the original 600 hospitals in our sample, we found that 2 were closed, bringing our total sample of eligible hospitals to 598.

We sent an electronic survey to the sampled hospitals between May 16, 2018, and July 23, 2018; 474 hospitals responded, a 79-percent response rate. We requested information on whether hospitals work with a federally listed PSO; why they did or did not; and what value and challenges they perceive from the PSO program if they do.

AHRQ Data

We requested data from AHRQ on its oversight of the PSO program from its start through 2017, including the following: the numbers of initial and continued PSO listings; the number of delisted PSOs and related information; the number and outcomes of compliance reviews; and the number of times that AHRQ provided technical assistance to PSOs, and the nature of that technical assistance.

Stakeholder Interviews

We conducted interviews with staff from a purposive sample of 9 hospitals and 12 PSOs. We use the data from these interviews as examples and to provide context, but do not use them to generalize to all hospitals or PSOs. We also interviewed AHRQ staff and others, including an attorney who works with PSOs and a representative from a professional association for PSOs.

Analysis

We analyzed data from our PSO survey to describe PSOs' characteristics, services offered, and experiences working with AHRQ. We also analyzed data from that survey to describe the subset of PSOs that work with hospitals. We produced estimates from our hospital survey data to describe the experiences of general acute-care hospitals with listed PSOs.

Some questions on our surveys offered response options on a 3-point or 4-point ranked scale. For example, for some questions, respondents could choose "very important," "somewhat important," "slightly important," or "not important." For others, they could choose from "major challenge," "minor challenge," or "not a challenge." We report our findings by aggregating all categories that positively identify something either as challenging or as important, for example.

Finally, we used data from our interviews with hospitals and PSOs to add context to our survey data and to gain additional detail on areas of interest that PSOs and hospitals identified.

Limitations

We did not independently verify the survey responses that PSOs and hospitals provided, nor did we independently verify the data that AHRQ provided on its oversight activities.

Data from the PSO survey represent the views and experiences of the 74 responding PSOs rather than all 82 PSOs.

In addition, because we limited the scope of our evaluation of the value of the PSO program to general acute-care hospitals participating in Medicare, this study does not reflect the experiences of other types of providers that work with PSOs.

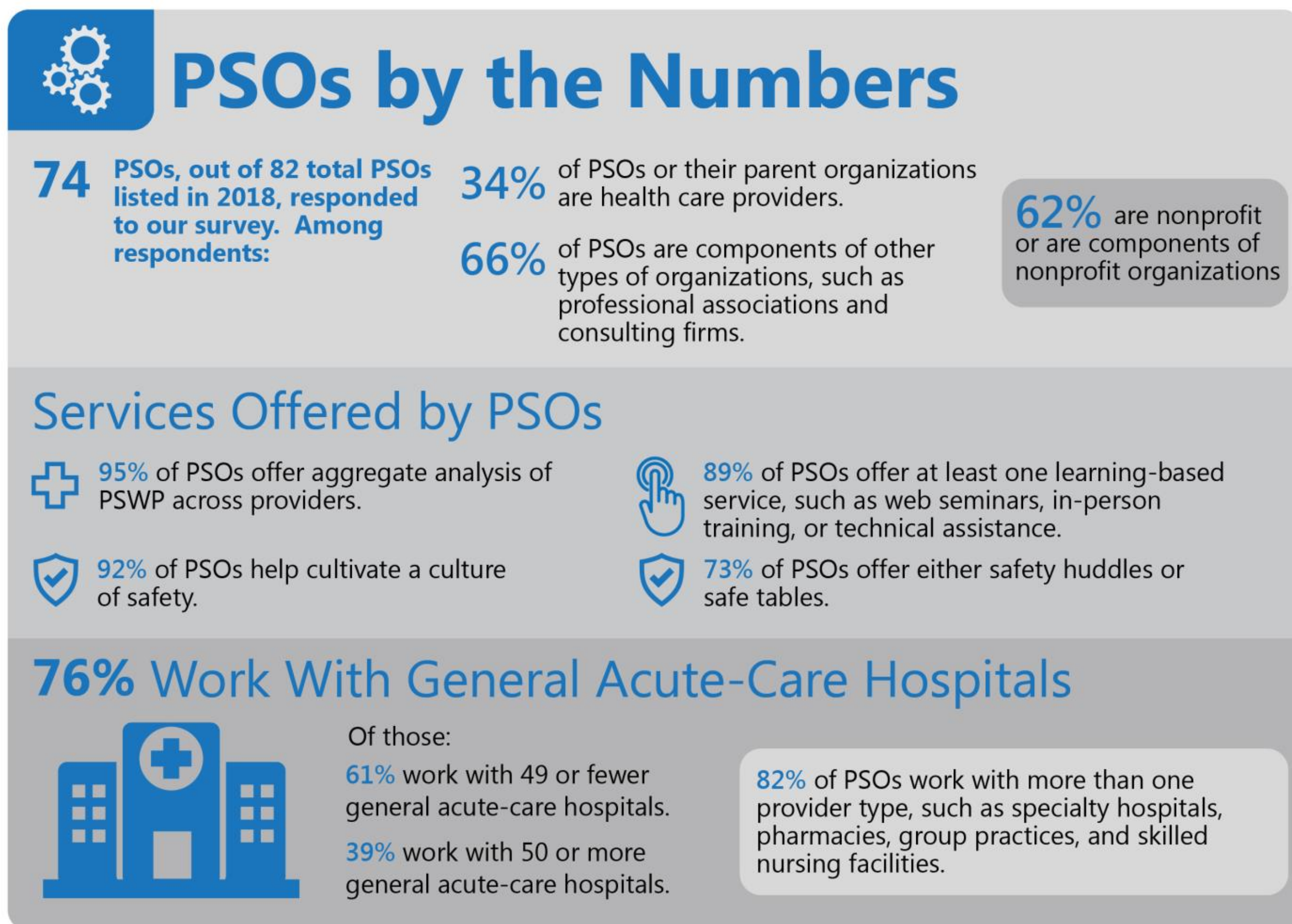
Standards

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.

Key Characteristics of the PSO Program

Not all PSOs are the same. Although they generally offer a similar array of services, they differ in other ways. For example, PSOs vary by size, profit status, and specialty.

Exhibit 3. PSOs by the Numbers



Source: OIG survey of PSOs, 2018.

FINDINGS

Over half of hospitals work with a PSO, and nearly all of them find the relationship valuable

Fifty-nine percent of general acute-care hospitals participating in Medicare work with a PSO. More than two-thirds of those hospitals (68 percent) have done so for 5 years or fewer. Among the most important reasons why hospitals choose to work with a PSO are the opportunity to improve patient safety (with 94 percent of hospitals citing it as very important in their decision to work with a PSO); the opportunity to learn from PSOs' analysis of patient safety data (with 87 percent citing it as very important), and the privilege and confidentiality protections for PSWP (with 83 percent citing this reason as very important).

Among hospitals that work with a PSO, nearly all (97 percent) find it valuable to work with a PSO and half rate it as very valuable.

Hospitals find that working with a PSO improved patient safety

Among hospitals that work with PSOs, 80 percent find that feedback and analysis on patient safety events have helped prevent future events, and 72 percent find that such feedback has helped them understand the causes of events. For example, one hospital told us that its PSO alerted its members about a malfunction with a certain medical device. This hospital was able to identify the device and resolve the malfunction. Although it can be difficult to identify events and quantify improvement, 63 percent of hospitals that work with PSOs believe that feedback and analysis from a PSO has made a measurable improvement in patient safety.[37]

80% of hospitals that work with a PSO found that the PSO's feedback and analysis was helpful to prevent future patient safety events

PSOs offer hospitals analysis and feedback of patient safety in several ways, including root-cause analyses of specific events and analysis of data aggregated from their members. A PSO may use its analysis of aggregate data to show members how their data compare to those of their peers; this service is known as benchmarking. Among hospitals that receive a benchmarking service, nearly all (96 percent) find it helpful.

Hospitals find PSO services related to knowledge-sharing and learning to be helpful

Among hospitals who say working with a PSO has been very valuable, nearly half volunteered that the value is in the ability to learn from other organizations. Working with a PSO allows hospitals to draw on the shared

knowledge of their fellow member-hospitals through peer-to-peer learning that would not otherwise be available to them.

One Hospital's Perspective

"Learning from other organizations in a safe environment has been extremely helpful. It assists us with identifying risks we may not have considered and decreases the chance of a harm occurring to our patients..."

A service called safe tables is one example of how PSOs facilitate peer-to-peer learning in a confidential environment. PSOs use safe tables to bring together staff from their provider members—either in person or virtually—to discuss patient safety topics, such as adverse events that have occurred at member institutions. PSO staff facilitate the meetings, which may include analysis of the causes of adverse events and possible solutions for preventing them in the future.

Both hospitals and PSOs find that safe tables are a valuable service. One PSO said that safe tables are among the most valuable services it offers, noting that its membership had quadrupled since it began offering them: "[E]ven though [providers] are hesitant to submit adverse events [to PSOs], they will talk in a protected environment." A physician we interviewed called safe tables "priceless," and noted that such discussions can change a hospital's culture. Nearly all (95 percent) hospitals that work with a PSO found that their PSOs have helped improve the culture of safety at their facilities. A culture of safety is one that (among other key features) enables individuals to report errors without fear of reprimand and to collaborate on solutions.[38]

Hospitals that do not participate in the program do not perceive it to be distinct from other patient safety efforts

For hospitals that do not participate in the PSO program, a perception that the program is redundant relative to other patient safety efforts is an important factor for 97 percent of such hospitals and a very important factor for 70 percent. For example, most hospitals that do not work with a PSO are working with a non-PSO entity (79 percent) to improve patient safety. Similarly, most (82 percent) believe that a PSO's functions are redundant to their internal efforts to improve patient safety.

97%

of hospitals that do not work with a PSO said redundancy was an important factor

Furthermore, hospitals perceive PSO reporting as being redundant to Federal and State reporting of patient safety data. Although the data that hospitals send to PSOs may be similar to what they send to these reporting systems, reporting to a PSO does not exempt them from government reporting requirements. About 80 percent of hospitals that do not work with a PSO cite Federal or

State redundancies in reporting as a factor in that decision.

Perceived redundancies in reporting and overlap with other patient safety programs may foster the impression that a PSO creates extra work, detracting from the value that hospitals perceive in working with a PSO. In fact, workload is an important factor for 87 percent of hospitals that do not participate in the program. Perceived lack of value is also an important factor in the decision not to work with a PSO for about two-thirds (67 percent) of the hospitals that do not participate. These perceptions may help explain why some PSOs fail to recruit even two providers—the minimum required by the Act—and relinquish their listing as a result.

One PSO's Perspective

Because the PSO program "overlaps with other initiatives… it can be challenging to recruit and engage members who have limited time and resources."

Finally, among hospitals that do not work with a PSO, lack of familiarity with the program was a factor for almost two-thirds (61 percent). Some hospitals volunteered that they wanted to learn more about the program.

Uncertainty over the program's legal protections and determining what information is protected can be challenging for hospitals

The Act enables the PSO program to offer legal protections for certain patient safety data that other programs cannot. AHRQ's website includes resources for understanding those protections. However, despite these available resources, uncertainty over the Act's legal protections for PSWP is a challenge for 27 percent of hospitals that work with a PSO, and a major challenge for 24 percent.

Concern over the protections may be heightened for providers in States where such protections have been challenged in court. For example, one PSO told us that some hospitals in Florida, where protections have been challenged in court, do not report patient safety information because of their uncertainty over legal protections.

A clear understanding of the Patient Safety Act's definitions is vital, because the legal protections apply only to information that meets the definition of PSWP. Fifty-seven percent of hospitals that work with PSOs found determining what constitutes PSWP to be a challenge; however, 43 percent did not find it challenging. Similarly, 56 percent of hospitals that work with PSOs find interpreting HHS guidance on the definition of PSWP to be challenging while 44 percent do not.

Hospitals' concerns over data protections may keep some hospitals from disclosing data to their respective PSOs and others from working with a PSO at all. Uncertainty over data protections was a factor for nearly three-quarters of hospitals that choose not to work with a PSO.

Hospitals' concerns over the legal protections create challenges for the PSOs that work with them. In fact, 48 of the 56 PSOs that work with hospitals find that hospitals' concerns over protections are challenging and 24 find them very challenging.

Although the Common Formats enable AHRQ to aggregate and analyze data, requiring them for the NPSD may slow its progress

One goal of the Patient Safety Act is to improve patient safety by (in part) using the NPSD to gather and aggregate data for national research and learning. Although the Act permits AHRQ to develop Common Formats, AHRQ faces a challenge universal to developing any standard—that a singular approach cannot fit every situation. Indeed, AHRQ intends for the Common Formats to facilitate national-level data aggregation and analysis, rather than to meet the unique needs of every provider and PSO. The Act does not require providers and PSOs to use the Common Formats, but AHRQ requires data that PSOs submit to the NPSD to be in the Common Formats.

Forty-two percent of PSOs surveyed cannot contribute to the NPSD because they do not use the Common Formats

Among the 74 PSOs that responded to our survey, 42 percent (31 of 74) neither accept data from members in the Common Formats nor translate data into the Common Formats (through a process called mapping). For some PSOs' members, using the Common Formats is not an option because none exist for the type of events they experience. In fact, nearly two-thirds of PSOs (46 of 74) reported that the lack of Common Formats for the data their members collect is a challenge to submitting data for the NPSD.

The Common Formats

The Act provided for development of common definitions and formats, known as the Common Formats, for reporting patient safety event data. The Common Formats enable AHRQ to aggregate and analyze patient safety data that PSOs submit to the NPSD.

Only 12 percent of PSOs (9 of 74) that use the Common Formats use them exclusively. Most PSOs that use them told us that they also accept data in other formats, such as those used by their members' risk management systems. PSOs' accepting data in multiple formats makes it easier for their members to submit data. Forty percent of PSOs that accept data in other formats (26 of 65) map the data into the Common Formats or engage a third party to do so, but many (47 of 74 PSOs) report that this process is challenging.

In the past few years, AHRQ has made progress in getting PSOs to submit data to the NPSD, with the number of records growing from 740,000 in 2017 to 1.8 million in 2019. According to AHRQ, 18 PSOs have submitted data to

the NSPD, with 3 PSOs submitting the bulk (87 percent) of the records. Because PSOs vary in the numbers of and types of providers they serve, some are likely to submit more data than others. In any case, the number of records the NPSD has received from a limited number of PSOs shows the potential for data aggregation if more PSOs submitted data.

Challenges with the Common Formats reflect the limits of using a standardized approach to capturing patient safety data

Despite having opportunities to provide input on the design of the Common Formats, over half of PSOs (40 of 74) told us that they do not capture enough information and nearly as many (31 of 74 PSOs) said they capture too much.

Furthermore, most PSOs (56 of 74) reported that the Common Formats are not useful for certain patient safety events. In some cases, such as anesthesia-related events, the Common Formats do not collect the type of information that PSOs find useful for learning from these events. One PSO that works with specialty hospitals told us that the Common Formats are designed for general acute-care hospitals, and as a result the Common Formats do not capture the type of information that a specialty hospital might find useful. For example, a rehabilitation hospital would find it useful to know contextual details that are specific to the rehabilitation setting, such as a fall's having occurred during a routine physical therapy session. One general acute-care hospital told us that these types of limitations with the Common Formats led it to use the "other" category to describe as many as half of its events. A PSO told us that as many as 80 percent of the patient safety events it receives fall into the "other" category. One consequence of this is that the Common Formats' recording of an "other" event does not capture enough information, or the right type of information, to make the data useful. Indeed, AHRQ told us that incomplete event data and having too many events described as "other" limits the usefulness of the data for analysis and learning.

The challenges with the Common Formats highlight the difficulty of developing a standard for the range of patient safety events that PSOs and their members face. This may explain why PSOs choose not to use the Common Formats and why more than half cite as a challenge the lack of clarity on how their submitting data for the NPSD would be valuable either to them as PSOs (42 of 74 PSOs) or valuable to their members (44 of 74 PSOs).

AHRQ provides technical assistance that PSOs find helpful, but its guidance on the program falls short of meeting PSOs' needs

Nearly all (43 of 47) PSOs that sought technical assistance from AHRQ over the past year found it helpful, and over half of those (27 of 47) said it was very helpful. Requests for technical assistance related to the PSO program increased from 350 in 2009 to 1,134 in 2017. One PSO we interviewed said that AHRQ is quick to respond to requests for technical assistance. Similarly, PSOs find AHRQ's other avenues of providing technical support helpful. For example, nearly all PSOs that attended AHRQ's annual meeting (60 of 64 PSOs) found it to be helpful, as did nearly all of the PSOs that had used AHRQ's website resources over the preceding year (66 of 70 PSOs). One PSO described the annual meeting as "a wonderful opportunity to share information with other PSOs and learn from other programs' patient safety activities." Several PSOs noted that AHRQ's website provides valuable information, with one PSO saying that it and its members "frequently accessed and utilized" AHRQ's website resources.

> **One PSO's Perspective**
>
> *"Resources provided through AHRQ have been supportive and educational in the day-to-day work of a PSO."*

However, PSOs struggle to interpret AHRQ's expectations for the processes of initial listing and continued listing. Although PSOs that completed the initial listing process and PSOs that had recently completed the continued listing process generally found AHRQ to be helpful with these processes, some PSOs reported challenges in interpreting AHRQ's expectations for meeting the requirements.[39] For example, nearly two-thirds of PSOs (44 of 72) found it challenging to interpret AHRQ's expectations for initial listing, with 18 of these reporting that it was a major challenge.[40] PSOs that underwent the continued listing process also reported challenges. Of the PSOs that underwent the process in the preceding year, nearly two-thirds (27 of 44) found it challenging to interpret AHRQ's expectations for the process, and 23 percent of these (10 of 44) reported that it was a major challenge. Some PSOs provided examples of challenges such as difficulty in determining exactly what they needed to prepare for the continued listing process, and AHRQ's being inconsistent in its expectations.

Although AHRQ provides technical assistance to PSOs, HHS delegated the responsibility for interpretation and enforcement of the legal protections to OCR. Therefore, AHRQ does not provide legal guidance to PSOs on the definition of PSWP. Accordingly, AHRQ told us that it refers PSOs with complex questions about legal protections to OCR or brokers a call between the PSO and OCR. The fact that hospitals and PSOs both cited the issue of the protections as a challenge suggests that additional support from AHRQ and OCR might be beneficial.

CONCLUSION AND RECOMMENDATIONS

Congress intended for the PSO program to be unique and powerful among patient safety programs. It is the first and only nationwide program that offers legal protections for providers to disclose patient safety events and learn from them. Where providers were once reluctant to discuss patient safety events for fear of litigation, they may now seek expert analysis from PSOs and discuss these events with peers that are fellow PSO members. Furthermore, through the NPSD, the PSO program is the only comprehensive program that aims to enable learning on a national scale about the causes of patient safety events.

The PSO program has the potential to improve health care. Indeed, this review shows that the program has made progress in its first decade. AHRQ has invested in developing and revising the Common Formats, and in creating the NPSD. Over half of hospitals work with a PSO; those hospitals find their participation valuable, with many reporting measurable improvement in patient safety. The number of records in the NPSD is growing, and AHRQ has launched a public-facing website for sharing NPSD data.

However, despite this progress, the PSO program faces challenges. A lack of hospital familiarity with the program hinders PSOs' ability to recruit more hospitals, and concerns over the program's legal protections may keep hospitals from fully engaging with PSOs. Furthermore, PSOs have not universally adopted the Common Formats. Ultimately, these challenges have slowed AHRQ's progress toward creating a robust NPSD. As a result, the PSO program has yet to realize its promise of enabling learning and advances in patient safety on a national scale. For the PSO program to fully realize its potential, AHRQ should do more to support and promote the program.

Therefore, we recommend that AHRQ:

Develop and execute a communications strategy to increase hospitals' awareness of the program and its value to participants

Lack of familiarity with and misperceptions of PSOs among hospitals are challenges that PSOs still face, 10 years after the program began.

Therefore, AHRQ should do more to promote the program by developing and executing a communications strategy. In doing so, AHRQ could work to engage provider associations, professional societies, risk management organizations, and other stakeholder organizations. As part of this outreach, AHRQ should explain how aspects like the legal protections and shared learning make working with a PSO different from other quality- and safety-related initiatives. Regarding the legal protections for PSWP, AHRQ

could reach out to OCR to discuss how the two can improve stakeholders' understanding of the legal protections. Such discussion could include assessing the potential for formalizing a pathway for PSOs and their members to contact OCR for timely, case-by-case guidance on the legal protections.

AHRQ could take advantage of the launch of the public-facing NPSD website and use it to promote the PSO program more broadly.

Take steps to encourage PSOs to participate in the NPSD, including accepting data into the NPSD in other formats in addition to the Common Formats

Nearly 10 years after OIG encouraged AHRQ to invest in the Common Formats, a number of PSOs (31 of 74) still do not use them. However, the NPSD accepts only data that is in the Common Formats, limiting its ability to aggregate data on a scale that would fulfill the promise of national learning.

For this reason, in addition to accepting data in the Common Formats, AHRQ should consider accepting data to the NPSD in other formats as well. In doing so, AHRQ could prioritize accepting data in existing reporting formats such as those used by State and other reporting systems. This might yield large gains in data for the NPSD while reducing redundancies in the reporting workload for providers. Furthermore, AHRQ should also explore advanced technologies that may enable the NPSD to accept and analyze unstructured data in the future.

Beyond accepting data in additional formats, AHRQ should take further steps to encourage providers and PSOs to submit data to the NPSD.

Such steps might include:

1. Developing a campaign to encourage providers and PSOs to address a specific, high-priority type of patient safety event. Central to the campaign would be submitting a critical mass of data about the event to the NPSD for analysis. AHRQ could use the resulting learning to provide feedback on preventing the event as an example of the NPSD's value.
2. Collecting and analyzing data on reasons why PSOs do not submit data to the NPSD. AHRQ could use that information to develop next steps for addressing challenges that PSOs face beyond what we identified within this report.

Such steps could increase the likelihood that PSOs will contribute data to the NPSD and offer a quicker path to fulfilling the promise of national learning envisioned within the Act.

Update guidance for PSOs on the initial and continued listing processes

AHRQ released a self-assessment tool—its only comprehensive guide on eligibility, listing, operational, and other requirements for PSOs—in September 2009, less than a year after publishing the final rule implementing the Patient Safety Act. Since issuing the self-assessment tool, AHRQ has had nearly 10 years of experience in working with PSOs with varying business models and approaches to meeting the requirements of the Patient Safety Act and the final rule.

To provide better guidance for PSOs on the initial and continued listing processes, AHRQ should first consider whether a self-assessment tool is the best format for guiding PSOs through these processes and whether this tool is adequate guidance on its own. AHRQ should then update the tool and/or produce additional guidance as appropriate.

AGENCY COMMENTS AND OIG RESPONSE

AHRQ concurred with our first and third recommendations, and partially concurred with our second recommendation.

Regarding our first recommendation, AHRQ said that it will develop and execute a communications strategy to increase hospitals' awareness of the PSO program and its value. The strategy will include a review of AHRQ's website and resources, and—subject to available resources—outreach to organizations of providers and other stakeholders. Also as part of its strategy, AHRQ will discuss with OCR how to improve stakeholder understanding of the PSO program's legal protections.

Regarding our second recommendation, AHRQ concurred with taking steps to encourage PSOs to participate in the NPSD, but it did not concur with accepting data to the NPSD in other formats. AHRQ stated that, subject to available resources, it will consider developing a campaign to focus on collecting data on a specific event type to encourage NPSD participation, and that it will discuss that possibility with PSOs at its 2020 PSO Annual Meeting. AHRQ will also explore the use of advanced technologies that might make it possible for the NPSD to accept unstructured data. AHRQ identified challenges to accepting data into the NPSD in existing formats in addition to the Common Formats but stated it could consider doing so should technological and other factors make it feasible.

Finally, regarding our third recommendation, AHRQ stated that it will revise its PSO self-assessment tool to more clearly link the contents to additional resources and tools it has developed based on experience with the PSO listing process.

For the full text of AHRQ's comments, see Appendix B.

APPENDIX A: Statistics for Responses to Select Items From Surveys

Survey of Hospitals

Description	Sample size	Point estimate	95% confidence interval
PSO participation			
Percentage of hospitals that work with a PSO	474	59.5%	55.3–63.5%
Percentage of hospitals that do not work with a PSO	474	40.5%	36.5–44.7%
Number of years the hospital has worked with a PSO			
Percentage of hospitals that have worked with a PSO for less than 1 year	282	8.5%	5.9–12.1%
Percentage of hospitals that have worked with a PSO for 1 to 5 years	282	59.2%	53.8–64.4%
Percentage of hospitals that have worked with a PSO for 6 years or more	282	32.3%	27.4–37.5%
Importance of opportunity to improve patient safety in deciding to work with a PSO			
Percentage of hospitals that found opportunity to improve patient safety very important	282	94.0%	90.8–96.1%
Percentage of hospitals that found opportunity to improve patient safety somewhat important	282	5.0%	3.1–7.9%
Percentage of hospitals that found opportunity to improve patient safety slightly important	282	1.1%	0.4–3.0%
Percentage of hospitals that found opportunity to improve patient safety not important	282	0%	0.1–2.2%

Description	Sample size	Point estimate	95% confidence interval
Importance of opportunity to learn from analysis of aggregate data from providers in deciding to work with a PSO			
Percentage of hospitals that found opportunity to learn from analysis very important	282	86.5%	82.4–89.8%
Percentage of hospitals that found opportunity to learn from analysis somewhat important	282	7.7%	7.7–14.5%
Percentage of hospitals that found opportunity to learn from analysis slightly important	282	2.8%	1.5–5.3%
Percentage of hospitals that found opportunity to learn from analysis not important	282	0%	0.1–2.2%
Importance of privilege and confidentiality protections for PSWP in deciding to work with a PSO			
Percentage of hospitals that found PSWP privilege and confidentiality protections very important	282	82.6%	78.1–86.4%
Percentage of hospitals that found PSWP privilege and confidentiality protections somewhat important	282	14.9%	11.4–19.2%
Percentage of hospitals that found PSWP privilege and confidentiality protections slightly important	282	1.8%	0.8–4.0%
Percentage of hospitals that found PSWP privilege and confidentiality protections not important	282	0.7%	0.2–2.5%
Value of Working with a PSO			
Percentage of hospitals that found working with a PSO very valuable	282	51.8%	46.3–57.2%
Percentage of hospitals that found working with a PSO somewhat valuable	282	37.6%	32.5–43.0%
Percentage of hospitals that found working with a PSO slightly valuable	282	7.8%	5.3–11.3%
Percentage of hospitals that found working with a PSO not valuable	282	2.8%	1.5–5.3%

Description	Sample size	Point estimate	95% confidence interval
Usefulness of PSO analysis in preventing future patient safety events			
Percentage of hospitals that found working with a PSO useful to preventing future patient safety events	282	80.1%	75.5–84.1%
Percentage of hospitals that found working with a PSO not useful to preventing future patient safety events	282	19.9%	15.9–24.6%
Usefulness of PSO analysis in understanding the causes of patient safety events			
Percentage of hospitals that found analysis from a PSO useful to understanding the cause of patient safety events	282	71.6%	66.5–76.3%
Percentage of hospitals that found analysis from a PSO not useful to understanding the cause of patient safety events	282	28.4%	23.7–33.5%
Measurable improvement in patient safety from PSO analysis			
Percentage of hospitals that found PSO analysis resulted in measurable improvement in patient safety	282	62.8%	57.4–67.9%
Percentage of hospitals that found PSO analysis did not result in measurable improvement in patient safety	282	37.2%	32.2–42.6%
Helpfulness of PSO analysis of PSWP from its members [i.e., benchmarking] to hospitals			
Percentage of hospitals that found PSO analysis of PSWP helpful	249	96.0%	93.0–97.7%
Percentage of hospitals that found PSO analysis of PSWP not helpful	249	4.0%	2.3–7.0%

Description	Sample size	Point estimate	95% confidence interval
Helpfulness of PSO service of cultivating a culture of safety to hospitals			
Percentage of hospitals that found PSO service of cultivating a culture of safety helpful	265	95.1%	92.0–97.0%
Percentage of hospitals that found PSO service of cultivating a culture of safety not helpful	265	4.9%	3.0–8.0%
Helpfulness of PSO service of safe tables/member convenings to hospitals			
Percentage of hospitals that found PSO service of safe tables/member convenings helpful	207	94.7%	91.0–96.9%
Percentage of hospitals that found PSO service of safe tables/member convenings not helpful	207	5.3%	3.1–9.0%
Lack of familiarity with the PSO program as a reason for not working with a PSO			
Percentage of hospitals that found lack of familiarity with the PSO program an important reason	192	60.9%	54.4–67.1%
Percentage of hospitals that found lack of familiarity with the PSO program not an important reason	192	39.1%	32.9–45.6%
At least one form of redundancy as a reason for not working with a PSO			
Percentage of hospitals that found at least one form of redundancy a very important reason	192	69.8%	63.4–75.5%
Percentage of hospitals that found at least one form of redundancy a somewhat important reason	192	20.3%	15.5–26.1%
Percentage of hospitals that found at least one form of redundancy a slightly important reason	192	7.3%	4.5–11.5%
Percentage of hospitals that found at least one form of redundancy not an important reason	192	2.6%	1.2–5.8%
Already working with another entity to improve patient safety (including nonlisted PSOs) as a reason for not working with a PSO			
Percentage of hospitals that found working with another entity to improve patient safety an important reason	192	79.2%	73.3–84.0%
Percentage of hospitals that found working with another entity to improve patient safety not an important reason	192	20.8%	16.0–26.7%

Description	Sample size	Point estimate	95% confidence interval
Redundancy to internal efforts as a reason for not working with a PSO			
Percentage of hospitals that found redundancy to internal efforts an important reason	192	81.8%	76.1–86.3%
Percentage of hospitals that found redundancy to internal efforts not an important reason	192	18.2%	13.7–23.9%
Redundancy to Federal reporting as a reason for not working with a PSO			
Percentage of hospitals that found redundancy to Federal reporting an important reason	192	83.3%	77.8–87.7%
Percentage of hospitals that found redundancy to Federal reporting not an important reason	192	16.7%	12.3–22.2%
Redundancy to State reporting as a reason for not working with a PSO			
Percentage of hospitals that found redundancy to State reporting an important reason	192	79.7%	73.9–84.5%
Percentage of hospitals that found redundancy to State reporting not an important reason	192	20.3%	15.5–26.1%
Workload as a reason for not working with a PSO			
Percentage of hospitals that found workload is an important reason	192	87.0%	81.9–90.8%
Percentage of hospitals that found workload is not an important reason	192	13.0%	9.2–18.1%
Lack of value as a reason for not working with a PSO			
Percentage of hospitals that found lack of value is an important reason	192	67.2%	60.7–73.1%
Percentage of hospitals that found lack of value is not an important reason	192	32.8%	27.0–39.3%

Description	Sample size	Point estimate	95% confidence interval
Uncertainty over privilege and confidentiality protections as a challenge to working with a PSO			
Percentage of hospitals that found uncertainty over privilege/confidentiality protections to be a major challenge	282	23.8%	19.5–28.7%
Percentage of hospitals that found uncertainty over privilege/confidentiality protections to be a minor challenge	282	27.0%	22.4–32.0%
Percentage of hospitals that found uncertainty over privilege/confidentiality protections not to be a challenge	282	49.3%	43.9–54.7%
Determining what constitutes PSWP as a challenge to working with a PSO			
Percentage of hospitals that found determining what constitutes PSWP a to be a challenge	282	57.1%	51.7–62.4%
Percentage of hospitals that found determining what constitutes PSWP not to be a challenge	282	42.9%	37.6–48.4%
Interpreting the 2016 HHS guidance document as a challenge to working with a PSO			
Percentage of hospitals that found interpreting the 2016 HHS guidance document to be a challenge	282	56.0%	50.6–61.3%
Percentage of hospitals that found interpreting the 2016 HHS guidance document not to be a challenge	282	44.0%	38.7–49.4%
Uncertainty of privilege and confidentiality protections as a reason for not working with a PSO			
Percentage of hospitals that found uncertainty of privilege and confidentiality protections an important reason	192	74.5%	68.3–79.8%
Percentage of hospitals that found uncertainty of privilege and confidentiality protections not an important reason	192	25.5%	20.2–31.7%

Survey of PSOs

Description	Percentage	Number/Total
PSO nonprofit status		
Percentage of PSOs that are nonprofit	62.2%	46/74
Percentage of PSOs that are not nonprofit	37.8%	28/74
Health care provider status of PSO or its parent company		
Percentage of PSOs or parent companies that are health care providers	33.8%	25/74
Percentage of PSOs or parent companies that are not health care providers	66.2%	49/74
Offering aggregate analysis of PSWP across providers		
Percentage of PSOs that offer aggregate analysis of PSWP across providers	94.6%	70/74
Percentage of PSOs that do not offer aggregate analysis of PSWP across providers	5.4%	4/74
Helping cultivate a culture of safety		
Percentage of PSOs that cultivate a culture of safety	91.9%	68/74
Percentage of PSOs that do not cultivate a culture of safety	8.1%	6/74
Offering at least one learning-based service		
Percentage of PSOs that offer at least one learning-based service	89.2%	66/74
Percentage of PSOs that do not offer at least one learning-based service	10.8%	8/74
Offering safe tables or safety huddles		
Percentage of PSOs that offer either safe tables, safety huddles, or both	73.0%	54/74
Percentage of PSOs that offer neither safe tables nor safety huddles	27.0%	20/74

Description	Percentage	Number/Total
Working with at least one general acute-care hospital		
Percentage of PSOs that work with at least one general acute-care hospital	75.7%	56/74
Percentage of PSOs that do not work with at least one general acute-care hospital	24.3%	18/74
Number of general acute-care hospitals with which PSO works		
0	24.3%	18/74
1 to 9	17.6%	13/74
10 to 49	28.4%	21/74
50 to 99	14.9%	11/74
100 or more	14.9%	11/74
Working with more than one provider type		
Percentage of PSOs that work with more than one provider type	82.4%	61/74
Percentage of PSOs that do not work with more than one provider type	17.6%	13/74
Hospital concerns about data protections as a challenge to PSOs		
Percentage of PSOs that find hospital concerns about data protections to be a challenge	85.7%	48/56
Percentage of PSOs that find hospital concerns about data protections not to be a challenge	14.3%	8/56
Hospitals not submitting data as a challenge to PSOs		
Percentage of PSOs that find hospitals not submitting data to be a challenge	62.5%	35/56
Percentage of PSOs that find hospitals not submitting data not to be a challenge	37.5%	21/56

Description	Percentage	Number/Total
Accepting data from members in Common Formats and/or translating data into Common Formats through mapping		
Percentage of PSOs that neither accept CF nor map	41.9%	31/74
Percentage of PSOs that do not accept CF but map	9.5%	7/74
Percentage of PSOs that accept CF but do not map	23.0%	17/74
Percentage of PSOs that accept CF and map	25.7%	19/74
A lack of Common Formats relevant to the data that PSOs' members collect as a challenge to PSOs		
Percentage of PSOs that found a lack of Common Formats relevant to the data that PSOs' members collect to be a challenge	62.2%	46/74
Percentage of PSOs that found a lack of Common Formats relevant to the data that PSOs' members collect not to be a challenge	37.8%	28/74
Format of patient safety reports accepted by PSOs		
Percentage of PSOs that accept patient safety reports in AHRQ's Common Formats	12.2%	9/74
Percentage of PSOs that accept patient safety reports in a format other than the CF	51.4%	38/74
Percentage of PSOs that accept patient safety reports in both	36.5%	27/74
Mapping data to the Common Formats		
Percentage of PSOs that map data to the Common Formats	40.0%	26/74
Percentage of PSOs that do not map data to the Common Formats	60.0%	39/74
Mapping data onto the Common Formats as a challenge to PSOs		
Percentage of PSOs that found mapping data onto the Common Formats to be a challenge	63.5%	47/74
Percentage of PSOs that found mapping data onto the Common Formats not to be a challenge	36.5%	27/74

Description	Percentage	Number/Total
Common Formats not capturing enough information as a challenge to PSOs		
Percentage of PSOs that found that the Common Formats do not capture enough information to be a challenge	54.1%	40/74
Percentage of PSOs that found that the Common Formats do not capture enough information not to be a challenge	46.0%	34/74
Common Formats capturing too much information as a challenge to PSOs		
Percentage of PSOs that found that the Common Formats capture too much information to be a challenge	41.9%	31/74
Percentage of PSOs that found that the Common Formats capture too much information not to be a challenge	58.1%	43/74
Usefulness of the Common Formats for certain types of patient safety events as a challenge to PSOs		
Percentage of PSOs that found usefulness of the Common Formats for certain types of patient safety events to be a challenge	75.7%	56/74
Percentage of PSOs that found usefulness of the Common Formats for certain types of patient safety events not to be a challenge	24.3%	18/74
Lack of clarity on how submitting to the NPSD would provide value to this PSO as a challenge		
Percentage of PSOs that found a lack of clarity on how submitting to the NPSD would provide value to this PSO to be a challenge	56.8%	42/74
Percentage of PSOs that found a lack of clarity on how submitting to the NPSD would provide value to this PSO not to be a challenge	43.2%	32/74

Description	Percentage	Number/Total
Lack of clarity on how submitting to the NPSD would provide value to PSOs' members as a challenge		
Percentage of PSOs that found a lack of clarity on how submitting to the NPSD would provide value to PSOs' members to be a challenge	59.5%	44/74
Percentage of PSOs that found a lack of clarity on how submitting to the NPSD would provide value to PSOs' members not to be a challenge	40.5%	30/74
Helpfulness of AHRQ with technical assistance over the past year		
Percentage of PSOs that found AHRQ to be very helpful with technical assistance	57.5%	27/47
Percentage of PSOs that found AHRQ to be somewhat helpful with technical assistance	21.3%	10/47
Percentage of PSOs that found AHRQ to be slightly helpful with technical assistance	12.8%	6/47
Percentage of PSOs that found AHRQ to not be helpful with technical assistance	8.5%	4/47
Helpfulness of AHRQ with their annual meeting over the past year		
Percentage of PSOs that found AHRQ's annual meeting to be helpful	93.8%	60/64
Percentage of PSOs that found AHRQ's annual meeting to not be helpful	6.3%	4/64
Helpfulness of AHRQ with website resources over the past year		
Percentage of PSOs that found AHRQ to be helpful with website resources	94.3%	66/70
Percentage of PSOs that found AHRQ to not be helpful with website resources	5.7%	4/70

Description	Percentage	Number/Total
Helpfulness of AHRQ with technical assistance over the past year		
Percentage of PSOs that found AHRQ to be very helpful with technical assistance	57.5%	27/47
Percentage of PSOs that found AHRQ to be somewhat helpful with technical assistance	21.3%	10/47
Percentage of PSOs that found AHRQ to be slightly helpful with technical assistance	12.8%	6/47
Percentage of PSOs that found AHRQ to not be helpful with technical assistance	8.5%	4/47
Helpfulness of AHRQ with their annual meeting over the past year		
Percentage of PSOs that found AHRQ's annual meeting to be helpful	93.8%	60/64
Percentage of PSOs that found AHRQ's annual meeting to not be helpful	6.3%	4/64
Helpfulness of AHRQ with website resources over the past year		
Percentage of PSOs that found AHRQ to be helpful with website resources	94.3%	66/70
Percentage of PSOs that found AHRQ to not be helpful with website resources	5.7%	4/70
Interpreting AHRQ's expectations for initial listing as a challenge to PSOs		
Percentage of PSOs that found interpreting AHRQ's expectations for initial listing to be a major challenge	25.0%	18/72
Percentage of PSOs that found interpreting AHRQ's expectations for initial listing to be a minor challenge	36.1%	26/72
Percentage of PSOs that found interpreting AHRQ's expectations for initial listing not to be a challenge	38.9%	28/72
Interpreting AHRQ's expectations for continued listing in the past year as a challenge to PSOs		
Percentage of PSOs that found interpreting AHRQ's expectations for continued listing to be a major challenge	22.7%	10/44
Percentage of PSOs that found interpreting AHRQ's expectations for continued listing to be a minor challenge	38.6%	17/44
Percentage of PSOs that found interpreting AHRQ's expectations for continued listing not to be a challenge	38.6%	17/44

APPENDIX B: Agency Comments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

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

Date: August 28, 2019

To: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
Department of Health and Human Services

From: Gopal Khanna
Director, Agency for Healthcare Research and Quality

Subject: OIG Draft Report – *Patient Safety Organizations: Hospital Participation, Value, and Challenges*. (OEI-06-17-00420)

Thank you for the opportunity to review the draft report entitled, *Patient Safety Organizations: Hospital Participation, Value, and Challenges* (OEI-06-17-00420) and for undertaking this important study. AHRQ appreciates this well-deserved recognition of the valuable contributions made by AHRQ-listed patient safety organizations (PSOs) not only to the providers they work with and to the safety of their patients, but also to the development of the Network of Patient Safety Databases (NPSD), an evolving resource for shared national learning about patient safety. AHRQ would like to acknowledge the diverse range of safety and quality improvement opportunities addressed by PSOs and the providers with whom they work in general acute care Medicare-participating hospitals—the setting of care that is addressed in this OIG report—as well as in many other settings and across a variety of topic areas (including but not limited to anesthesiology, cancer treatment, dentistry, emergency care, general and specialty medical care in various settings, home health and hospice, long-term care, mental health, pediatrics, pharmacy, radiology, rehabilitation, renal dialysis, and surgery). This Report also highlights the continuing success of the landmark Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), which offers unique and powerful support for patient safety and quality improvement work across the United States. Considering the voluntary nature of working with a PSO as established by the Patient Safety Act, the number and diversity of providers and PSOs that choose to make use of its provisions to support their patient safety and quality improvement work are important indicators of the significance of this law and its application.

AHRQ has the following specific responses to each of the OIG's recommendations:

1. **Recommendation #1**: AHRQ should develop and execute a communications strategy to increase hospitals' awareness of the program and its value to participants.

   AHRQ concurs with this recommendation and will work with the AHRQ Office of Communications to develop and execute a communications strategy aimed at increasing hospitals' awareness of the PSO program and its value. The strategy will include:

A. Review of the AHRQ PSO website and its materials

In 2014, AHRQ restructured the PSO website (See www.pso.ahrq.gov) toward its primary audiences. These were determined to be providers, PSOs listed by AHRQ, and entities interested in becoming a PSO. Prominence was given to features that would enhance provider experience in identifying PSOs of interest to them and resources to help them better understand the program. A PSO selection tool was added to enable providers and other users to filter the list of PSOs by various categories, such as PSO specialty, provider types served, types of services provided, and geographic region served. The site also includes information for providers interested in working with a PSO to reduce unnecessary hospital readmissions as required by the Affordable Care Act of 2010. Other resources were eventually added, including a video entitled, "Working with a PSO – One Approach," to help providers with understanding Patient Safety Act concepts such as "patient safety evaluation system" and "patient safety work product (PSWP)"; an on-demand webinar highlighting "Benefits of AHRQ Patient Safety Organizations (PSOs): Success Stories from Hospital PSO Members"; a brochure entitled "Choosing a Patient Safety Organization: Tips for Hospitals and Health Care Providers," which explains the benefits of working with an AHRQ-listed PSO, including the potential for Federal privilege and confidentiality protections; and PSO success stories from the field, to illustrate how working with a PSO can facilitate dramatic improvements in patient safety and the quality of care in many health care settings. AHRQ also makes the success stories available at the Agency's website (See www.ahrq.gov) to provide exposure to a broader audience.

In June 2019, AHRQ launched the Network of Patient Safety Databases (NPSD) and made available dashboards reflecting more than 1.1 million records submitted by PSOs to the NPSD (See www.ahrq.gov/NPSD).

In response to this recommendation, subject to the availability of resources, AHRQ will conduct a review of the PSO website and, where necessary and appropriate, revise its current approach to presenting resources targeting providers with an emphasis on increasing hospitals' awareness of the PSO program. Any changes will be announced to a broad audience using relevant AHRQ GovDelivery lists.

B. Outreach to provider associations, professional societies, risk management organizations and other stakeholder organizations.

Subject to the availability of resources, AHRQ will identify strategies that would be appropriate for the agency to undertake for outreach to promote the benefits of working with a PSO to members of major national hospital associations, hospital risk management organizations and appropriate hospital professional societies and to build awareness of the PSO program among hospitals. It should be noted that the same questions about perceived challenges of working with a PSO were asked of hospitals that were unfamiliar with the Patient Safety Act and those that are knowledgeable. As the unique benefits of working with an AHRQ-listed PSO would

not have been evident to the hospitals that lack familiarity with the Patient Safety Act, some of the findings (for example, perceptions of "redundancy") are difficult to interpret. Nonetheless, AHRQ will offer the resources listed in A. above and, if needed, will develop additional resources to explain how aspects such as the Patient Safety Act's confidentiality and privilege protections and the types of services that can be offered differentiate working with an AHRQ-listed PSO from other quality and safety-related resources.

C. Work with the HHS Office for Civil Rights (OCR) to discuss how to improve stakeholder understanding of the legal protections.

AHRQ has worked closely with OCR since the promulgation of the Patient Safety Rule to jointly address issues that impact the Patient Safety Organizations program. This relationship has been formalized in an ongoing interagency agreement between AHRQ and OCR. AHRQ will reach out to OCR leadership to discuss how best to improve stakeholders' understanding of the Patient Safety Act's legal protections and OCR's interpretation and enforcement of the confidentiality protections of the Patient Safety Act. AHRQ will explore with OCR the potential for the design and development of new educational materials, technical assistance resources, and approaches for dissemination regarding the confidentiality requirements of the Patient Safety Act and related matters such as protecting the security of PSWP.

With respect to direct technical assistance for PSOs, AHRQ and OCR have an ongoing, well-established mechanism to arrange for timely technical assistance by OCR for PSOs. This collaborative arrangement will remain in place, and the two agencies can explore possible ways to enhance the accessibility of this resource to PSOs.

2. **Recommendation #2**: AHRQ should take steps to encourage PSOs to participate in the Network of Patient Safety Databases (NPSD), including accepting data into the NPSD in other formats in addition to the Common Formats.

AHRQ concurs with this recommendation to the extent that it suggests AHRQ take steps to encourage PSOs to submit data to the NPSD.

We note that AHRQ already conducts activities relevant to this recommendation, including working with stakeholders who are willing to have AHRQ adapt for national use elements from event reporting formats that are widely recognized and used in particular specialty areas as was done for Common Formats for Event Reporting - Community Pharmacy.

In response to this recommendation, subject to the availability of resources, AHRQ will consider developing a campaign to focus on a specific event type, as OIG suggested. AHRQ will open discussions at the 2020 PSO Annual Meeting about the interest and commitment by PSOs to do so.

We also concur with the suggestion that AHRQ explore the use of advanced technologies that might, in the future, make it possible for the NPSD to accept unstructured data. As the lead research Agency for patient safety, AHRQ will monitor the development of the science to determine when the viability and accuracy of methods supporting such technology is sufficiently mature to consider for application in the specific situation of the NPSD.

In response to the suggestion that AHRQ might encourage submission of data to the NPSD by "collecting and analyzing data on reasons why PSOs do not submit more data to the NPSD," AHRQ will consider the feasibility of collecting and analyzing data to ascertain whether there are specific clinical and patient-safety-related issues with certain Common Formats data elements that PSOs can identify as barriers to use of the Common Formats and submission of data to the NPSD. However, AHRQ does not concur with the recommendation to collect and analyze data as specifically described in this recommendation, because AHRQ is already aware of a number of reasons why PSOs do not submit data to the NPSD that AHRQ has no ability to address. Foremost among them is that submission of data to the NPSD is entirely voluntary. PSOs are (almost entirely) private businesses. As there is no federal funding to support PSOs, those that submit data to the NPSD volunteer to do so entirely at their own expense. PSOs make choices for various business reasons that support their own missions and business models.

AHRQ also does not concur with the recommendation to the extent that it encourages AHRQ to "…accept data into the NPSD in other formats in addition to the Common Formats." AHRQ disagrees that accepting data exclusively in the Common Formats "limit[s] its ability to aggregate data on a scale that fulfills the promise of national learning." To the contrary, it is this common data structure that makes it possible for the NPSD to fulfill its statutory mandate to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported…." (42 U.S.C. § 299b-23(a)). Given the current state of technology, there could be no national aggregation and analysis for national learning if the NPSD were to accept data in a variety of reporting formats. Additionally, for many alternative formats of reporting, it is unclear how such data could be rendered nonidentifiable, as required by the statute. Furthermore, while, technically, accepting data in other formats may "yield large gains in data for the NPSD," it is unclear what purpose the NPSD having such data would serve absent the ability to aggregate and analyze such data. As such, it seems that encouraging providers to submit such data that currently could not be utilized by the NPSD would increase providers' reporting workload, with no associated advance in learning, rather than "reduc[e] redundancies," as suggested in this recommendation.

Nevertheless, should technological advances or other factors make it feasible to do so in a manner consistent with the requirements of the Patient Safety Act in the future, AHRQ could consider the possibility of accepting data into the NPSD in other formats at that time.

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3. **Recommendation #3**: AHRQ should update guidance for PSOs on the initial and continued listing processes.

AHRQ concurs with this recommendation as it pertains to the Compliance Self-Assessment Guide and in response, AHRQ will revise this Guide to more clearly link the contents to the many additional resources and tools AHRQ has developed and made available since 2009 based on experience with the PSO listing process. A self-assessment approach to learning is especially valuable for PSOs and prospective PSOs, as they are a highly diverse group of entities, each with a unique approach and business plan for offering PSO services.

It should be noted that the Compliance Self-Assessment Guide is not the only strategy AHRQ currently uses to provide comprehensive technical assistance regarding initial and continued listing. On the "Home" page of the AHRQ PSO website, links to "Become a PSO" and "Maintain a PSO Listing" are also prominently featured. Each web page contains a user-friendly overview of important points for PSOs to consider before and subsequent to initial listing, with links to pertinent resources on key points. Every entity and every AHRQ-listed PSO that contacts AHRQ to inquire about initial or continued listing has a preliminary discussion with a PSO team member who points to resources specific to its particular questions, and is offered as many technical assistance calls as needed with the PSO team (including OCR where relevant).

We look forward to following up with you regarding our activities related to the above recommendations. Please feel free to contact Dr. Jeff Brady, Director, Center for Quality Improvement and Patient Safety with any questions.

Gopal Khanna

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To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

ENDNOTES

[1] James, J.T. 2013. "A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care." *Journal of Patient Safety*, Vol. 9(3): 122-128.
[2] 73 Fed. Reg. 70732 (Nov. 21, 2008).
[3] Ibid.
[4] 42 U.S.C. § 299b-22.
[5] 42 U.S.C. § 299b-23.
[6] Institute of Medicine, *To Err Is Human: Building A Safer Health System*, November 1999. Accessed at http://nationalacademies.org/hmd/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx on September 15, 2017.
[7] About 13.5 percent of hospitalized beneficiaries experienced adverse events resulting in serious harm, and an additional 13.5 percent experienced events that resulted in temporary harm. See OIG, *Adverse Events in Hospitals: A National Incidence Among Medicare Beneficiaries*, November 2010. Accessed at https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf on September 18, 2017.
[8] 71 Fed. Reg. 28701 (May 17, 2006).
[9] 73 Fed. Reg. 70732 (Nov. 21, 2008).
[10] AHRQ, "Frequently Asked Questions," *Patient Safety Organization (PSO) Program*. Accessed at https://www.pso.ahrq.gov/faq#BenefitstoHealthcareProviders on September 4, 2019.
[11] Ibid.
[12] The Office for Civil Rights is responsible for overseeing the confidentiality protections for PSWP.
[13] 42 U.S.C. § 299b-21(7)(A)(i).
[14] 42 CFR § 3.204(a)(1).
[15] 42 CFR § 3.204(a)(2).
[16] 42 CFR § 3.204(a)(3).
[17] 81 Fed. Reg. 32655 (May 24, 2016).
[18] 42 U.S.C. § 299b-23(a).
[19] 42 U.S.C. § 299b-23(c).
[20] The Act directs the Secretary to include information resulting from analyses of the NPSD in HHS's annual quality reports.
[21] Government Accountability Office, *Patient Safety Act: HHS Is in the Process of Implementing the Act, So Its Effectiveness Cannot Yet Be Evaluated*. January 2010. Available online at http://www.gao.gov/new.items/d10281.pdf.
[22] 42 CFR 3.102(b)(2)(iii).
[23] P.L. No. 109-41 § 2, PHSA, § 924, 42 U.S.C. § 299b-24.
[24] 42 CFR 3.104.
[25] P.L. No. 109-41 § 2, PHSA, § 924, 42 U.S.C. 299b–24(a)(2).
[26] PSOs listed prior to the effective date of the final rule implementing the Patient Safety Act (January 19, 2009) had to apply for a new initial listing after the effective date of the final rule.
[27] 42 CFR 3.108(e).
[28] P.L. No. 109-41 § 2, PHSA, § 926, 42 U.S.C. 299b-25.
[29] 42 CFR 3.304(b).
[30] *The Department of Financial and Professional Regulation v. Walgreen Co*, 970 N.E.2d 552 (Ill. 2012).
[31] *Tibbs v. Bunnell,* 448 S.W.3d 796 (Ky. 2014).
[32] *Charles v. Southern Baptist Hosp. of Florida, Inc*., 209 So. 3d 1199 (Fla. Jan. 31, 2017).
[33] *Tibbs v. Bunnell*, 136 S. Ct. 2504 (June 27, 2016).
[34] *S. Baptist Hosp. of Fla., Inc. v. Charles*, 138 S. Ct. 129 (Oct. 2, 2017).
[35] *Baptist Health Richmond, Inc. v. Clouse*, 497 S.W.3d 759 (Ky. Sept. 22, 2016).
[36] 81 Fed. Reg. 32656 (May 24, 2016).
[37] OIG, *Hospital Incidence Reports Do Not Capture Most Patient Harm* (OEI-06-09-00091), January 2012. Accessed at https://oig.hhs.gov/oei/reports/oei-06-09-00091.pdf on July 24, 2019.
[38] AHRQ, *Patient Safety Primer*. January 2019. Available online at https://psnet.ahrq.gov/primers/primer/5/Culture-of-Safety.
[39] We define "recently" as those PSOs that completed continued listing within the year prior to receiving our survey in May 2018.
[40] All but 2 of the 74 PSOs that responded to our survey recalled their experiences with initial listing. The remaining two respondents were unable to answer this question.

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