January 2010

PATIENT SAFETY ACT

HHS Is in the Process of Implementing the Act, So Its Effectiveness Cannot Yet Be Evaluated

GAO

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Why GAO Did This Study

The Institute of Medicine (IOM) estimated in 1999 that preventable medical errors cause as many as 98,000 deaths a year among hospital patients in the United States. Congress passed the Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act) to encourage health care providers to voluntarily report information on medical errors and other events— patient safety data—for analysis and to facilitate the development of improvements in patient safety using these data. The Patient Safety Act directed GAO to report on the law's effectiveness.

This report describes progress by the Department of Health and Human Services, Agency for Healthcare Research and Quality (AHRQ) to implement the Patient Safety Act by (1) creating a list of Patient Safety Organizations (PSO) so that these entities are authorized under the Patient Safety Act to collect patient safety data from health care providers to develop improvements in patient safety, and (2) implementing the network of patient safety databases (NPSD) to collect and aggregate patient safety data. These actions are important to complete before the law's effectiveness can be evaluated. To do its work, GAO interviewed AHRQ officials and their contractors. GAO also conducted structured interviews with officials from a randomly selected sample of PSOs.

View GAO-10-281 or key components.
For more information, contact Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov.

What GAO Found

AHRQ has made progress listing 65 PSOs as of July 2009. However, at the time of GAO's review, few of the 17 PSOs randomly selected for interviews had entered into contracts to work with providers or had begun to receive patient safety data. PSO officials told GAO that some PSOs were still establishing aspects of their operations; some were waiting for AHRQ to finalize a standardized way for PSOs to collect data from providers; and some PSOs were still engaged in educating providers about the confidentiality protections offered by the Patient Safety Act.

AHRQ is in the process of developing the NPSD and its associated components—(1) the common formats PSOs and providers will be required to use when submitting patient safety data to the NPSD and (2) a method for making patient safety data non-identifiable, or removing all information which could be used to identify a patient, provider, or reporter of patient safety information. If each of these components is completed on schedule, AHRQ officials expect that the NPSD could begin receiving patient safety data from hospitals by February 2011. AHRQ officials could not provide a time frame for when they expect the NPSD to be able to receive patient safety data from other providers. AHRQ also has preliminary plans for how to allow the NPSD to serve as an interactive resource for providers and PSOs and for how AHRQ will analyze NPSD data to help meet certain reporting requirements established by the Patient Safety Act. According to AHRQ officials, plans for more detailed analyses that could be useful for identifying strategies to reduce medical errors will be developed once the NPSD begins to receive data.

Intended Flow of Information to and from the NPSD
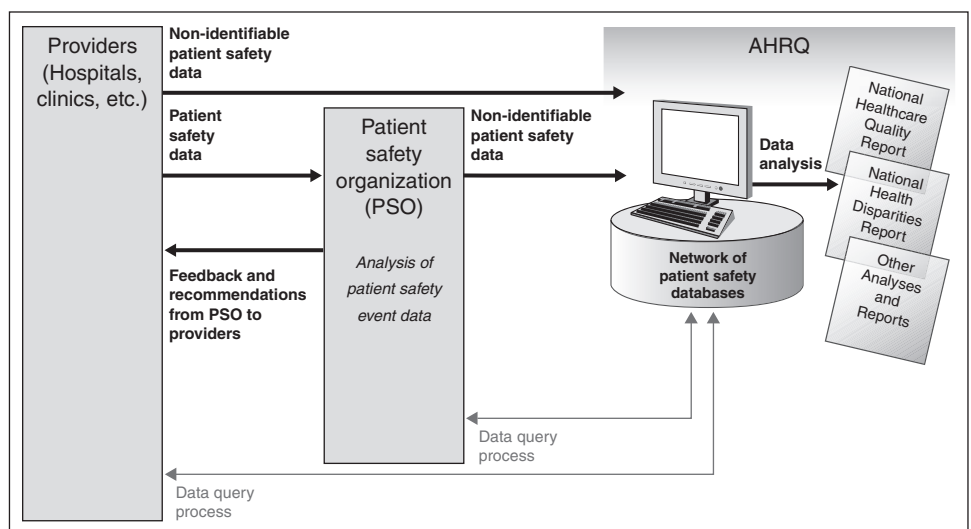
Source: GAO analysis of AHRQ documents.

The Department of Health and Human Services provided technical comments on a draft of this report, which we have incorporated as appropriate.

United States Government Accountability Office

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January 29, 2010

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

Research has shown that serious injuries or deaths resulting from medical care are both common and often preventable. In a frequently cited report, the Institute of Medicine (IOM) estimated in 1999 that preventable medical errors cause as many as 98,000 deaths a year among hospital patients in the United States.[1] The IOM identified several mechanisms for improving patient safety, including the use of medical error reporting systems to gather and analyze information on medical errors in order to prevent them from occurring in the future. The IOM report noted, however, that health care providers are often reluctant to report or disclose their medical errors and to participate in related learning efforts out of fear of incurring legal liability or professional sanctions. To address these concerns, the IOM report recommended the expanded use of voluntary medical error reporting systems that allow confidential reporting. The report also recommended that Congress provide legal protections to prevent the unauthorized disclosure of information collected and reported by providers for the purpose of improving patient safety.

At the time of the IOM's 1999 report, several states operated mandatory systems for the reporting of serious medical errors–those resulting in death or serious injury–but these reporting systems were primarily used to hold providers accountable for their errors and often involved public

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[1]Institute of Medicine, *To Err is Human: Building a Safer Health System* (Washington, D.C.: National Academy Press, 1999).

GAO-10-281 Patient Safety Act Implementation

disclosure. In contrast, confidential, voluntary systems for reporting of medical errors, designed primarily for developing improvements in patient safety, were less common and less widely used. Partially in response to the IOM report, Congress passed the Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act) to encourage health care providers to voluntarily report information on patient safety events and to facilitate the development and adoption of interventions and solutions to improve patient safety.[2]

To achieve these goals, the Patient Safety Act directed the Department of Health and Human Services (HHS) to create a list of public or private organizations known as Patient Safety Organizations (PSO). Listing by HHS indicates that PSOs are authorized to serve providers as independent patient safety experts and to receive data regarding patient safety events that will be considered privileged and confidential.[3] The Patient Safety Act prohibits the unauthorized disclosure of certain types of data regarding patient safety events that providers send to listed PSOs.[4] To facilitate the development of improvements in patient safety, the Patient Safety Act also requires PSOs to certify that they will analyze data regarding patient safety events, provide feedback to providers, and develop and disseminate information on ways providers can improve patient safety. By serving multiple providers and aggregating data regarding patient safety events, the Patient Safety Act intends for PSOs to help providers better understand the underlying causes of patient safety events and develop solutions to prevent or reduce the frequency of such events.

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[2]Throughout this report, we use the term patient safety events to include serious errors or system failures that caused harm to a patient, near misses in which an error or system failure occurred but the patient was not harmed, and unsafe conditions having the potential to cause harm.

[3]As defined by the Patient Safety Act, the term "provider" includes hospitals, health care practitioners, or any other individual or entity licensed or otherwise authorized under state law to provide health care services, or specified by the Secretary of HHS in regulations.

[4]The Patient Safety Act describes these data. Among other things, the data may include information on the type of event that occurred such as a medication error, fall, or hospital acquired infection. The data may also include the results of analyses conducted by the provider, information on whether the patient was harmed or not, and factors that may have contributed to the event such as poor staff communication, equipment failure, or lack of proper supervision.

To support PSOs and providers in their efforts to develop and adopt improvements in patient safety, the Patient Safety Act directed HHS to create a network of patient safety databases (NPSD). The Patient Safety Act specifies that the NPSD is to collect and aggregate non-identifiable data regarding patient safety events voluntarily submitted to it by PSOs and providers.[5] The law does not require PSOs or providers to submit data to the NPSD. The law also specifies that the NPSD should serve as a resource that health care providers, PSOs, and others can use to develop improvements in patient safety. Specifically, by facilitating the aggregation and analysis of patient safety data from providers nationwide, the NPSD is intended to assist PSOs and providers in identifying underlying patterns and trends associated with patient safety events. In addition, the Patient Safety Act also requires HHS to use data from the NPSD to analyze national and regional statistics, including trends and patterns in patient safety events, and to report on effective strategies for reducing patient safety events and increasing patient safety. HHS has delegated responsibility for listing PSOs, implementing and maintaining the NPSD, and analyzing data submitted to the NPSD to the Agency for Healthcare Research and Quality (AHRQ).

The Patient Safety Act requires GAO to report to Congress by February 1, 2010, on the law's effectiveness in accomplishing its purpose. Although the Patient Safety Act was enacted in July 2005, the law did not specify a time frame for implementation. Final regulations to implement the act became effective on January 19, 2009. In this report, we describe the progress AHRQ has made in (1) listing PSOs, including PSO efforts to serve providers, and (2) implementing the NPSD. These actions by AHRQ are important to complete before the law's effectiveness can be evaluated. In addition, because participation—including submission of data on patient safety events—by PSOs and providers is voluntary, their actions may also contribute to the law's effectiveness in accomplishing its purpose.

To describe the progress AHRQ has made in listing PSOs, we interviewed AHRQ and other HHS officials and reviewed relevant documents, including regulations, policies, and guidelines. We also conducted structured interviews with officials from 17 randomly selected PSOs, representing 26 percent of those listed as of July 2009, to obtain

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[5]In general, non-identifiable patient safety data are data which are not likely to identify a patient, provider, or certain other persons who report patient safety information to providers or PSOs. See 42 C.F.R. § 3.212.

information on the extent to which the PSOs have begun to collect and analyze patient safety data and provide feedback to providers. Although our sample was representative of listed PSOs, our findings from these interviews cannot be generalized to all PSOs. Furthermore, we did not speak directly with health care providers regarding their use, or potential use, of PSOs. To describe the progress AHRQ has made in implementing the NPSD, we interviewed officials at AHRQ and its contractors, and we reviewed relevant documents including contracts, time lines, and progress reports. In addition, we also obtained, for context, information on other established patient safety reporting systems, as AHRQ's efforts to list PSOs and implement the NPSD are relatively new. Specifically, we identified examples of how selected, established patient safety reporting systems encourage reporting of patient safety event information by providers and facilitate the development of improvements in patient safety. We present these examples and related methodology in appendix I.

We conducted our work from March 2009 to January 2010 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

Background

AHRQ and the Office for Civil Rights (OCR) within HHS share responsibility for implementing the Patient Safety Act. AHRQ is responsible for listing PSOs, providing technical assistance to PSOs, implementing and maintaining the NPSD, and analyzing the data submitted to the NPSD. OCR has responsibility for interpreting, implementing, and enforcing the confidentiality protections.[6] To help implement the Patient

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[6]AHRQ is the lead federal agency for supporting research designed to improve the quality of health care, reduce health care costs, improve patient safety, decrease medical errors, and broaden access to essential services. AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access. OCR also has responsibility for enforcing the health information privacy and security rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Safety Act, AHRQ and OCR developed the legislation's implementing regulations, which took effect January 19, 2009.[7]

PSOs

The Patient Safety Act establishes criteria that organizations must meet and required patient safety activities that the organizations must perform after being listed as PSOs. The criteria include an organizational mission to improve patient safety and the quality of health care delivery; use of collected data to provide direct feedback and assistance to providers to minimize patient risk; staff who are qualified to perform analyses on patient safety data; and adequate policies and procedures to ensure that patient safety data are kept confidential. Required PSO activities include activities such as efforts to improve patient safety and the quality of health care delivery. (See app. II for the complete list of criteria and required PSO activities as specified in the Patient Safety Act.) The criteria allow for many types of organizations to apply to AHRQ to be listed as a PSO. These organizations may include public and private entities, for-profit and not-for-profit organizations, and entities that are a component of another organization, such as a hospital association or health system.

A PSO must attest for the initial listing period that it will comply with the criteria and that it has policies and procedures in place that will allow it to perform the required activities of a PSO. When reapplying for subsequent 3-year listing periods, a PSO must attest that it is complying with the criteria and that it is in fact performing each of the required activities. The regulations require AHRQ staff to review written PSO applications documenting PSO attestations to each of the statutory criteria and required activities. In the case of certain PSOs that are component organizations, the regulations also require the applicant to complete an additional set of attestations and disclosure statements detailing the relationship between the component and parent organizations. The regulations require that after AHRQ staff review the application materials and related information, the applicant will be listed, conditionally listed, or denied.[8]

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[7]AHRQ and OCR developed the implementing regulations as a part of a team of officials from the HHS Office of the Secretary. These implementing regulations are found at Part 3, title 42, Code of Federal Regulations.

[8]The regulations allow applicants to be conditionally listed if they have been denied listing in the past or had a prior listing revoked.

Legal Protections for Patient Safety Data

When a provider elects to use the services of a listed PSO, the Patient Safety Act provides privilege and confidentiality protections[9] for certain types of data regarding patient safety events that providers collect for the purposes of reporting to a PSO.[10] In general, the Patient Safety Act excludes the use of patient safety data in civil suits, such as those involving malpractice claims, and in disciplinary proceedings against a provider. While certain states have laws providing varying levels of privilege and confidentiality protections for patient safety data, the Patient Safety Act provides a minimum level of protection.

Regulations implementing the Patient Safety Act address the circumstances under which patient safety data may be disclosed, such as when used in criminal proceedings, authorized by identified providers, and among PSOs or affiliated providers.[11] OCR has the authority to conduct reviews to ensure that PSOs, providers, and other entities are complying with the confidentiality protections provided by the law. OCR also has the authority to investigate complaints alleging that patient safety data has been improperly disclosed and to impose a civil money penalty of up to $11,000 per violation.[12]

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[9]The Patient Safety Act provides that patient safety data are privileged and confidential information. In general, privileged and confidential data are data to which access is restricted to persons or entities with certain legal rights to access the data based on, for example, the relationship between a PSO and provider. See 42 U.S.C. § 299b-22.

[10]The Patient Safety Act creates a special designation for data that meet these criteria– patient safety work product. Patient safety work product may include information on the type of event that occurred such as a medication error, fall, or hospital acquired infection. The data that comprise patient safety work product may also include the results of analyses conducted by the provider, information on whether the patient was harmed or not, and factors that may have contributed to the event such as poor staff communication, equipment failure, or lack of proper supervision. Patient safety work product under the act includes data regarding patient safety events that (1) have been assembled or developed by a provider for reporting to a listed PSO or developed by a listed PSO for conducting patient safety activities that could result in improved outcomes, quality, or safety, or (2) represent an analysis of information that the provider intends to submit to a listed PSO. For the purposes of this report, we use the term patient safety data to refer to patient safety work product as used in the Patient Safety Act.

[11]See 42 C.F.R. § 3.204 et seq.

[12]See 42 USC § 299(f); 42 C.F.R. § 3.404 (2009).

The NPSD and Requirements for Submitting Data to the NPSD

The Patient Safety Act requires HHS to create and maintain the NPSD as a resource for PSOs, providers, and qualified researchers.[13] The law specifies that the NPSD must have the capacity to accept, aggregate, and analyze non-identifiable patient safety data voluntarily submitted to the NPSD by PSOs, providers, and other entities.[14] Providers may submit non-identifiable data directly to the NPSD, or work with a PSO to submit patient safety data. Neither PSOs nor providers are required by either the Patient Safety Act or regulation to submit data to the NPSD. Figure 1 shows the intended flow of patient safety data and other information among providers, PSOs, and the NPSD.

Figure 1: Intended Flow of Information to and from the NPSD
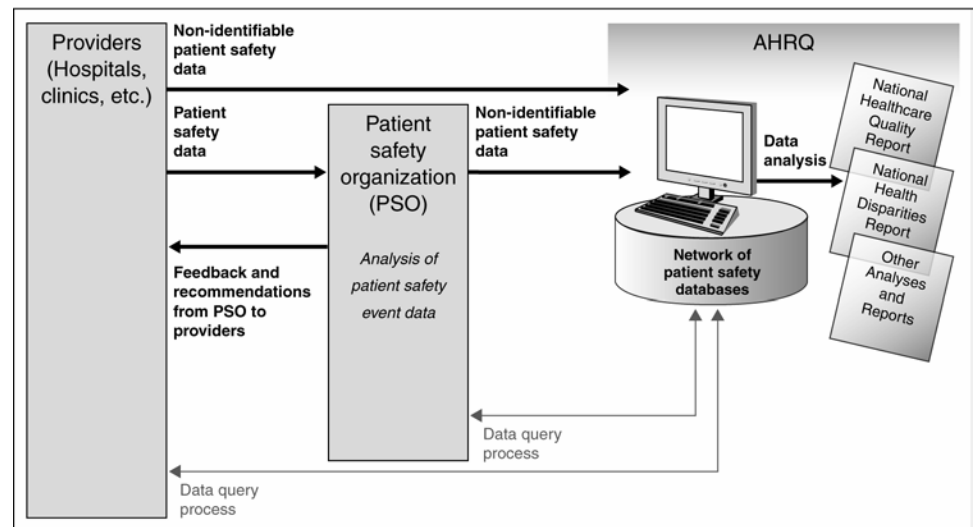
Source: GAO analysis of AHRQ documents.

Note: Submission of patient safety data from a provider to a PSO, from a provider to the NPSD, or from a PSO to the NPSD is voluntary. Before patient safety data can be transmitted to the NPSD, it must be made non-identifiable–that is, have any information removed that could be used to identify a patient, provider, or reporter of patient safety information.

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[13]The act does not specify what qualifications a researcher should have to be able to access the NPSD.

[14]Certain demonstration projects funded by HHS, such as the Patient Safety and Medical Liability Reform Demonstration Projects (2009), have posted notices indicating that HHS will require grant recipients to submit patient safety data to the NPSD as a part of the evaluation phase of the demonstration projects.

The Patient Safety Act authorizes HHS to develop common formats for reporting patient safety data to the NPSD. According to the Patient Safety Act, these formats may include the necessary data elements to be collected and provide common and consistent definitions and a standardized computer interface for processing the data.[15] While most U.S. hospitals have some type of internal reporting system for collecting data on patient safety events,[16] they often have varying ways of collecting and organizing their data.[17] This variation makes it difficult to accurately compare patient safety events across systems and providers[18] and can be a barrier to developing solutions to improve patient safety.[19] If providers or PSOs choose to submit patient safety data to the NPSD, AHRQ requires that these data be submitted using the common formats, because using the common formats is necessary so that data in the NPSD can be aggregated and analyzed. Aggregation and analysis of data is important for developing the "lessons learned" or "best practices" across different institutions that may help improve patient safety.[20]

The Patient Safety Act and its implementing regulations provide additional measures PSOs must follow whether or not they intend to submit the data they collect to the NPSD. The Patient Safety Act regulations require PSOs to collect patient safety data from providers in a standardized manner that permits valid comparisons of similar cases among similar providers, to the extent to which these measures are practical and appropriate. To meet this requirement, the regulation specifies that PSOs must either (1) use the common formats developed by AHRQ when collecting patient safety data

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[15]The Patient Safety Act requires the common formats comply to the extent practicable with the administrative simplification provisions of part C of title XI of the Social Security Act, which provides standards for information transactions and data elements.

[16]In addition, numerous private organizations, such as the Institute for Safe Medication Practices and the AABB, operate systems for collecting data on patient safety events that also use their own ways of collecting data.

[17]AHRQ, "Common Formats: Facilitating Learning from Patient Safety Data. What Are Common Formats?" http://www.pso.ahrq.gov/formats/brochurecmnfmt.htm (accessed Oct. 21, 2009).

[18]Liam J. Donaldson, "In Terms of Safety," *International Journal for Quality in Health Care*, vol. 18, no. 5 2006.

[19]Richard Thomson, Pierre Lawalle, Heather Sherman, Peter Hibbert, and Gerard Castro, "Towards an International Classification for Patient Safety: a Delphi survey," *International Journal for Quality in Health Care*, Vol. 21, No.1, 2009, p.9.

[20]Thomson, et al. p.11.

from providers, (2) utilize an alternative format that permits valid comparisons among providers, or (3) explain to AHRQ why it would not be practical or appropriate to do so. The Patient Safety Act also requires any data regarding patient safety events that is submitted to the NPSD be non-identifiable. According to the Patient Safety Act, users can access non-identifiable patient safety data only in accordance with the confidentiality protections established by the Patient Safety Act. The Patient Safety Act's regulations provide technical specifications for making patient safety data non-identifiable.[21]

Finally, the Patient Safety Act states AHRQ must analyze the data that are submitted to the NPSD and include these analyses in publicly available reports. Specifically, under the Patient Safety Act, AHRQ is required to submit a draft report on strategies to improve patient safety to the IOM within 18 months of the NPSD becoming operational and a final report to Congress 1 year later. The Patient Safety Act requires this report to include effective strategies for reducing medical errors and increasing patient safety, as well any measures AHRQ determines are appropriate to encourage providers to use the strategies, including use in any federally funded programs. In addition, the Patient Safety Act states HHS must use data in the NPSD to analyze national and regional statistics, including trends and patterns of health care errors, and include any information resulting from such analyses in its annual reports on health care quality.[22]

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[21]See Subpart C, Part 3, title 42 of the Code of Federal Regulations. In the preamble to the regulations, HHS notes that, to the extent that patient safety data is also protected health information under the HIPAA Privacy Rule, a use or disclosure of such data would also have to comply with applicable HIPAA Privacy Rule requirements. See 73 Fed. Reg. at 70773-74.

[22]In 1999, Congress directed AHRQ to produce an annual report, starting in 2003, on health care quality in the United States (42 U.S.C. 299b-2(b)(2)). AHRQ's annual National Healthcare Quality Report and National Healthcare Disparities Report are designed to summarize data across a wide range of patient needs, including staying healthy, getting better, living with chronic illness and disability, and coping with the end of life. These reports track quality across nine condition areas and describe the effectiveness, safety, timeliness, extent to which care is patient-centered, and efficiency of medical care delivery in the United States. The reports present data at the national and state levels, where state-level data are available, and also incorporate methodological improvements in quantifying trends in health care quality and disparities.

AHRQ Has Listed PSOs, but Few PSOs We Interviewed Have Begun Serving Providers

AHRQ listed 65 PSOs from November 2008 to July 2009.[23] However, few of the 17 PSOs we randomly selected to interview had entered into contracts or other business agreements with providers to serve as their PSO, and only 3 PSOs reported having begun receiving patient safety data or providing feedback to providers. PSO officials identified several reasons why they have not yet engaged with providers. Some PSOs are still establishing various aspects of their operations; some are waiting for the common formats for collecting patient safety data to be finalized by AHRQ; and some are still engaged in marketing their services and educating providers about the federal confidentiality protections offered by the Patient Safety Act.

As of July 2009, AHRQ Had Listed 65 PSOs Representing a Variety of Organizations

Although the regulations implementing the Patient Safety Act did not become effective until January 19, 2009,[24] AHRQ began listing PSOs earlier, in November 2008.[25] By July 2009, AHRQ had listed 65 PSOs in 26 states and the District of Columbia.[26] AHRQ officials told us that in listing PSOs they accepted PSOs' attestations that the PSOs met the certification requirements established in the Patient Safety Act—that is, to be a listed PSO, an entity must have policies and procedures in place to perform the required activities of a PSO and will comply with additional criteria for listing.[27] For continued listing beyond the initial period, PSOs must attest that they have contracts with more than one provider and are in fact performing each of the required activities.

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[23]AHRQ has continued to list additional PSOs since this time.

[24]HHS released a proposed rule in February 2008.

[25]HHS issued interim guidance prior to the publication of the final rule. PSOs that were listed prior to the publication of the final rule on November 21, 2008, were required to complete a supplemental attestation process to verify their meeting of the requirements contained in the final rule.

[26]PSOs are not limited to providing services in the state in which they are located. While some are targeting providers in a single state or region, others plan to offer their services nationwide.

[27]To balance the streamlined PSO listing process specified in the Patient Safety Act, HHS included a provision in the regulations allowing it to conduct announced or unannounced reviews or site visits to verify PSO compliance with the listing requirements. In September 2009, AHRQ announced plans to conduct on-site compliance reviews of PSOs approximately once every 6 years beginning in 2010 and issued a guide to assist PSOs in preparing for such reviews.

The 65 PSOs AHRQ had listed represent a wide range of organizations, including some that provided patient safety services for many years prior to being listed as well as new organizations specifically established to function as a PSO under the Patient Safety Act.[28] AHRQ officials told us that the organizations listed as PSOs include consulting firms that have provided patient safety services for a range of providers and specialties, as well as organizations with a focus on patient safety in a specific area such as medical devices, hand hygiene, or pediatric anesthesia. The listed PSOs also include vendors of patient safety reporting software and components of state hospital associations.

AHRQ officials told us that the services PSOs deliver to individual providers will likely vary, depending on the specific contractual or other business agreements the PSOs establish with providers.[29] For example, a small hospital may want to contract with a PSO to provide all its internal quality improvement services, while a large hospital may just contract with a PSO to obtain the legal protections under the Patient Safety Act and to contribute data to the NPSD. While officials of 13 of the 17 PSOs we interviewed indicated they provided some patient safety services prior to being listed, all 17 PSOs stated that the services they planned to make available included the collection and analysis of patient safety data, the de-identification of patient safety data for submission to the NPSD, feedback, and patient safety training.

Few Listed PSOs We Interviewed Have Begun to Serve Providers

While AHRQ has listed 65 PSOs, few PSOs we interviewed have entered into contracts or other business agreements with providers to serve as their PSO. Only 4 of the 17 listed PSOs we interviewed had any contracts or other agreements with providers to serve as their PSO. Furthermore, according to PSO officials, only 3 of these PSOs had begun to receive patient safety data or provide feedback to providers.[30] PSO officials identified several reasons why they had yet to begin working with

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[28]A full list of listed PSOs can be found on the AHRQ Web site at: http://www.pso.ahrq.gov/listing/psolist.htm.

[29]The services PSOs provide can vary, as long as the PSO meets the requirement that across all the providers it serves, it performs the activities specified in the Patient Safety Act.

[30]While many of the organizations that obtained listing as a PSO offered patient safety services prior to being listed, in order to remain listed as a PSO they must have a contract with more than one provider within each 24-month period that begins on the date the PSO was initially listed.

providers and receiving patient safety data as of July 2009. These reasons include the following:

The need to complete the development of various components of their business operations. Some PSO officials we interviewed told us they still need to determine various components of their operations. For example, officials from some PSOs told us they have yet to determine their fee structure for working with providers. Officials from 6 of 17 PSOs we interviewed stated they were or would be contracting with other PSOs to receive services, such as information technology systems support or data security. Nine PSOs reported they had not yet determined whether they would be contracting for some services. In addition, while officials from most of the PSOs we interviewed indicated they planned to submit patient safety data to the NPSD, 4 had not yet determined how they will make data non-identifiable before sending it to the NPSD.

The need to obtain AHRQ's final common formats for collecting data on patient safety events. Officials from some PSOs we interviewed indicated they needed the common formats to be finalized by AHRQ before beginning to work with providers. While use of AHRQ's common formats to collect data from providers is not required under the regulations, most PSOs we interviewed plan to use the common formats for collecting data on patient safety events and submitting these data to the NPSD. Officials from 7 of the 17 PSOs we interviewed said they plan to require providers to submit data using the common formats, and 4 PSOs said they will not require them of providers but will either convert the reports they receive to the common formats or adapt their existing reporting system to include the common formats.[31]

The need to educate providers about the federal confidentiality protections. Officials from several of the 17 PSOs we interviewed told us they faced challenges in addressing provider concerns related to the scope of the confidentiality protections and that these concerns needed to be addressed before providers would be willing to engage the services of a PSO. Some of these PSO officials described challenges in communicating details of the confidentiality protections. According to AHRQ officials, the rules for when, where, and how patient safety data are protected from

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[31]Three of the 17 PSOs said they will not require use of the common formats due to a lack of compatibility with their organization's model or the cost associated with adapting their existing system, and 3 other PSOs said they did not yet know whether they would be requiring use of the common formats.

disclosure are both complex and interrelated with the privacy rules for protected health information under HIPAA. AHRQ officials acknowledged the need to work with PSOs to clarify the rules governing the confidentiality of patient safety data so PSOs can better communicate these to providers. AHRQ officials indicated they would address these issues in upcoming quarterly conference calls they hold with PSO representatives. (See appendix I for examples of ways established patient safety reporting systems communicate legal protections for providers and the data they submit.)

AHRQ Is in the Process of Implementing the NPSD and Has Developed Preliminary Plans for Using NPSD Data

AHRQ is in the process of implementing the NPSD and developing its associated components that are necessary before the NPSD can receive patient safety data—(1) the common formats PSOs and providers will be required to use if submitting patient safety data to the NPSD and (2) a method for making these data non-identifiable. If each of these components is completed on schedule, AHRQ officials expect that the NPSD could begin receiving patient safety data from hospitals in February 2011. AHRQ officials could not provide a time frame for when they expect the NPSD to be able to receive patient safety data from other providers. AHRQ also has preliminary plans for how to allow the NPSD to serve as an interactive resource for providers and PSOs and for how AHRQ will analyze NPSD data to help meet its reporting requirements under the Patient Safety Act.

AHRQ Is in the Process of Developing the NPSD, the Common Formats for Hospitals to Submit Data to the NPSD, and a Method for Making Data Non-identifiable

AHRQ is in the process of developing the NPSD, and AHRQ officials expect that the NPSD could begin receiving patient safety data from hospitals by February 2011. Specifically, AHRQ established a 3-year contract with Westat effective September of 2007 to develop the NPSD,[32] which is being set up as a database that AHRQ officials stated is essential for meeting the requirements of the act. AHRQ and Westat officials told us that completion of the NPSD depends on both the development of the common formats that will be used to submit patient safety data to the NPSD and on the development of a method for making the data non-identifiable. If each of these components is completed on schedule, AHRQ officials expect that the NPSD could begin to receive patient safety data from hospitals by February 2011.

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[32]Westat provides research services under contract to government and private sector organizations.

AHRQ is finalizing the common formats that PSOs and hospitals will be required to use if submitting patient safety data to the NPSD. AHRQ officials expect that the common formats could be available for hospitals to use in submitting data electronically to the NPSD by September 2010. AHRQ began developing the common formats for hospitals in 2005 by reviewing the data collection methods of existing patient safety systems. In 2007, AHRQ contracted with the National Quality Forum (NQF) to assist with the collection and assessment of public comments on a preliminary version of the common formats that was released in August 2008.[33] These common format forms are used to collect information on patient safety events, including information about when and where an event occurred, a description of the event, and patient demographic information.[34] AHRQ issued the common formats for hospitals in paper form in September 2009, and is in the process of making electronic versions available for hospitals and PSOs to use when submitting data to the NPSD. Specifically, AHRQ officials told us that they are in the process of developing technical specifications that private software companies and others can use to develop electronic versions of the common formats. According to AHRQ officials, hospitals and PSOs will need these electronic versions of the common formats in order to submit data to the NPSD. Their current project plan indicates that the technical specifications will be completed by March 2010. AHRQ officials estimate that electronic versions of the common formats could be available to hospitals and PSOs by September 2010.

AHRQ officials stated that they expect eventually to develop common formats for providers in other health care settings, such as nursing homes and ambulatory surgical centers. Furthermore, AHRQ officials told us that that they plan on developing future versions of the common formats capable of collecting data from the results of root cause analyses that providers may conduct.[35] However, AHRQ officials were unable to provide an estimate for when the common formats for other providers will be

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[33]The National Quality Forum is a nonprofit organization created in 1999 to promote patient protections and health care quality through measurement and public reporting.

[34]AHRQ has posted the common formats for hospitals at the following Web site: https://www.psoppc.org/web/patientsafety.

[35]Root cause analysis involves in-depth analysis by individuals most familiar with the patient safety event to determine why the event occurred and what can be done to prevent it from occurring again.

available or when the capability to collect information from root cause analyses will be available.

The Patient Safety Act also requires that data submitted to the NPSD be made non-identifiable by removing information that could be used to identify individual patients, providers, or facilities. To help PSOs and providers meet this requirement, AHRQ contracted with the Iowa Foundation for Medical Care (IFMC)[36] to operate a PSO Privacy Protection Center (PPC) that will develop a method for making patient safety data non-identifiable and assist PSOs and providers by removing any identifiable patient or provider information from the data before submission to the NPSD. Current AHRQ and PPC project plans indicate that the PPC should be ready to receive and make patient safety data non-identifiable beginning in September 2010. AHRQ officials told us that this process involves not only removing information from each record that could be used to identify patients, providers, or reporters of patient safety information, but also determining whether identities could be determined from other available information and using appropriate methods to prevent this type of identification from occurring.[37] AHRQ officials told us that PPC officials are working with experts to develop the PPC's method for making data non-identifiable.[38]

AHRQ officials stated that their rationale for establishing the PPC was to determine a method for making data non-identifiable, provide a cost savings for PSOs, encourage data submission to the NPSD, and create consistency in the non-identifiable data that are submitted to the NPSD. According to AHRQ officials, the PPC will provide its services to PSOs at no charge and will submit non-identifiable patient safety data on behalf of PSOs to the NPSD.[39] However, PSOs are not required to use the PPC and may choose to make their patient safety data non-identifiable internally or with the help of a contractor of their choice.

[36]The Iowa Foundation for Medical Care is a health care quality improvement and medical information management organization.
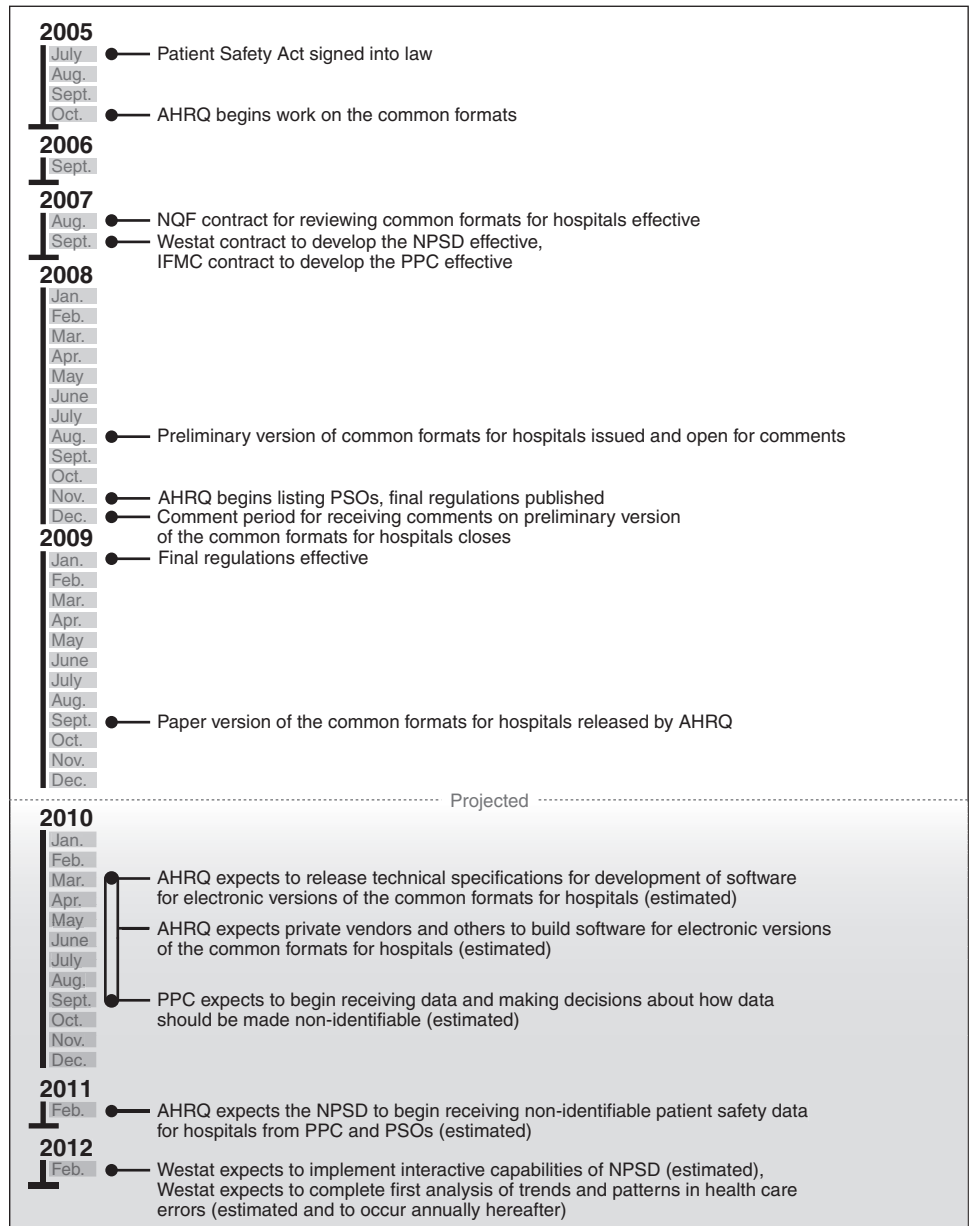
[37]For example, if a patient experienced a rare type of patient safety event, it might be possible for identification to be made based on news sources or anecdotal information even if the record does not include the patient's name. To prevent such identification, appropriate adjustments must be made to the data.

[38]IFMC officials stated that these experts include officials from the Census Bureau and the National Center for Health Statistics.

[39]Patient safety data are only submitted to the NPSD if the provider elects to do so.

AHRQ project plans indicate that the PPC will be able to submit data to the NPSD beginning in February 2011, approximately 5 months after the PPC begins receiving data from hospitals. AHRQ officials stated that this time period is necessary, in part, because the PPC needs to begin receiving data before it can determine if its method for rendering data non-identifiable is appropriate or needs to be adjusted. For example, if the PPC receives a sufficient volume of data, then officials expect to be able to submit data on individual patient safety events and have it remain non-identifiable. If the volume of data is too low, however, PPC officials expect to have to aggregate data from individual events so that it remains non-identifiable once submitted to the NPSD, in which case AHRQ officials stated they may delay submission of data to the NPSD until a sufficient volume is received. AHRQ officials noted that it is impossible to determine in advance the volume of data that will be submitted to the PPC due to the voluntary nature of submissions. As a result, the level of detail that will exist in the NPSD data cannot be determined in advance of data being received and processed by the PPC. Figure 2 summarizes key dates in AHRQ's efforts to develop the NPSD and its related components.

Figure 2: Timeline for Developing the NPSD

2005
July — Patient Safety Act signed into law
Aug.
Sept.
Oct. — AHRQ begins work on the common formats

2006
Sept.

2007
Aug. — NQF contract for reviewing common formats for hospitals effective
Sept. — Westat contract to develop the NPSD effective,
IFMC contract to develop the PPC effective

2008
Jan.
Feb.
Mar.
Apr.
May
June
July
Aug. — Preliminary version of common formats for hospitals issued and open for comments
Sept.
Oct.
Nov. — AHRQ begins listing PSOs, final regulations published
Dec. — Comment period for receiving comments on preliminary version
of the common formats for hospitals closes

2009
Jan. — Final regulations effective
Feb.
Mar.
Apr.
May
June
July
Aug.
Sept. — Paper version of the common formats for hospitals released by AHRQ
Oct.
Nov.
Dec.

Projected

2010
Jan.
Feb.
Mar. — AHRQ expects to release technical specifications for development of software
Apr. for electronic versions of the common formats for hospitals (estimated)
May — AHRQ expects private vendors and others to build software for electronic versions
June of the common formats for hospitals (estimated)
July
Aug.
Sept. — PPC expects to begin receiving data and making decisions about how data
Oct. should be made non-identifiable (estimated)
Nov.
Dec.

2011
Feb. — AHRQ expects the NPSD to begin receiving non-identifiable patient safety data
for hospitals from PPC and PSOs (estimated)

2012
Feb. — Westat expects to implement interactive capabilities of NPSD (estimated),
Westat expects to complete first analysis of trends and patterns in health care
errors (estimated and to occur annually hereafter)

Source: GAO.

Note: The timeline identifies actions that have a focus on hospitals. AHRQ officials could not provide a time frame for when they expect common formats to be developed for providers other than hospitals, or when the NPSD would be able to receive patient safety data from these providers.

AHRQ Has Preliminary Plans For How to Meet Requirements for Use of NPSD Data, Though AHRQ Officials Have Identified Limitations to the Types of Analyses That Will Be Conducted

The Patient Safety Act requires that the NPSD serve as an interactive resource for providers and PSOs, allowing them to conduct their own analyses of patient safety data. To meet this requirement, AHRQ has developed plans to allow providers to query the NPSD to obtain information on patient safety events, including information on the frequencies and trends of such events. AHRQ's contract with Westat to construct the NPSD includes a series of tasks for developing, testing, and implementing this interactive capability of the NPSD. The contract specifies that these interactive capabilities will be available within 12 months of the NPSD beginning to receive patient safety information. Based on AHRQ's estimate that the NPSD may be operational by February 2011, the interactive capabilities of the NPSD could be available by February 2012. However, AHRQ officials indicated that they had not yet determined the specific types of information that will be available to PSOs and providers as this will depend, in part, on the level of detail that is included in the NPSD data after the data are made non-identifiable.

The Patient Safety Act also states that HHS must use the information reported into the NPSD to analyze national and regional statistics, including trends and patterns of health care errors, and to identify and issue reports on strategies for reducing medical errors and increasing patient safety after the NPSD becomes operational. To do this, AHRQ has developed preliminary plans for analyzing the data that will be submitted to the NPSD. According to AHRQ officials, these plans specify how the agency will analyze NPSD data to determine trends and patterns, such as the frequency with which certain types of adverse events happen across providers based on the data they may submit to the NPSD. However, AHRQ has yet to develop plans for more detailed analyses of NPSD data that could be useful for identifying strategies to reduce medical errors. Officials explained that these plans will not be developed until the NPSD begins receiving data and they are able to determine the level of detail in the data and what analyses it will support.

Despite the potential for standardization provided by the common formats, AHRQ officials have identified important limitations in the types of analyses that can be performed with the data submitted to the NPSD. For example, AHRQ officials explained that because submissions to the NPSD are voluntary, the trends and patterns produced from the NPSD will not be nationally representative and, therefore, any analyses conducted cannot be used to generate data that are generalizable to the entire U.S. population. In addition, officials stated that the results from some analyses may be unreliable because there is no way to control for duplicate entries into the NPSD, which could occur if a provider submits a single patient

safety event report to more than one PSO. Finally, AHRQ officials noted that it will be difficult to determine the prevalence or incidence of adverse events in specific populations. They told us that determining prevalence or incidence rates requires information on the total number of people at risk for such events, and that the patient safety data submitted to the NPSD will not include this information. (See appendix I for more information about the ways established patient safety reporting systems analyze data to develop solutions that improve patient safety.)

Concluding Observations

AHRQ is still in the early stages of listing PSOs and developing plans for how it will analyze NPSD data and report on effective strategies for improving patient safety, as required under the Patient Safety Act. As a result, we cannot assess whether, or to what extent, the law has been effective in encouraging providers to voluntarily report data on patient safety events and to facilitate the development and adoption of improvements in patient safety. In addition, because improvements to patient safety depend on the voluntary participation of providers and PSOs, it remains uncertain whether the goals of the Patient Safety Act will be accomplished even after AHRQ completes its implementation. For example, providers will have to decide whether to work with a PSO and the extent to which they will report patient safety data to both the PSO and the NPSD. Whether the process results in specific recommendations for improving patient safety will depend on the volume and quality of the data submitted and on the quality of the analyses conducted by both PSOs and by AHRQ. Finally, if these recommendations are to lead to patient safety improvements, providers must recognize their value and take actions to implement them.

Agency Comments

The Department of Health and Human Services reviewed a draft of this report and provided technical comments, which we have incorporated as appropriate.

We will send copies of this report to the Secretary of Health and Human Services and other interested parties. In addition, the report is available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have questions about this report, please contact me at (202) 512-7114 or kohnl@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in appendix III.

Linda T. Kohn

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Director, Health Care

Appendix I: Examples from Established Patient Safety Reporting Systems

Because the Agency for Healthcare Research and Quality's (AHRQ) efforts to list Patient Safety Organizations and implement the Network of Patient Safety Databases are relatively new but some other patient safety reporting systems are already established, we identified examples of how selected established patient safety reporting systems encourage reporting of patient safety event information by providers and facilitate the development of improvements in patient safety. We judgmentally selected five established patient safety reporting systems from a list of such systems compiled by AHRQ. We selected systems that collected data for learning purposes and that appeared in a literature review we conducted of 45 relevant articles in peer-reviewed, trade, or scholarly publications published since January 2000.[1] After selecting the systems, we conducted structured interviews with representatives of these systems to identify examples of ways that these systems encouraged providers to submit patient safety data for analysis and used the data collected by their systems to help develop improvements in patient safety. The system representatives we interviewed provided common examples that we have grouped into four areas:

- Practices that encourage providers to learn from patient safety data, rather than blame individuals;

- Communication intended to clearly explain legal protections for providers and the data they submit;

- Data collection tools intended to standardize the data providers submit;

- Data analyses that produce actionable feedback.

Practices that encourage providers to learn from patient safety data, rather than blame individuals. Representatives from all five patient safety reporting systems we reviewed said their systems encourage providers to learn from patient safety data as a way to improve patient

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[1]To conduct our literature review we used search terms relevant to the field of patient safety reporting systems, including terms such as patient safety, patient safety organizations, adverse events, database, or quality improvement.

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safety, and not blame individuals for an event.[2] According to system representatives, one way they did this was to emphasize the value of the data collected by the system for learning ways to reduce the risk that a certain event will recur. For example, representatives from one system said they created posters to hang in health care facilities from which the system collected patient safety data. Representatives from this system explained that the posters described a patient safety event about which the system received data as well as the solutions the system developed to improve patient safety. Another practice representatives said they used is allowing providers to submit data anonymously. Four out of five system representatives said their systems offered providers a way to submit data anonymously.

Communication intended to clearly explain legal protections for providers and the data they submit. Many of the representatives we interviewed from patient safety reporting systems told us that their systems communicate information intended to clearly explain the legal protections afforded providers and the patient safety data they submit. For example, one system in our review provided guidance for providers on how to clearly label data to invoke the confidentiality protections associated with patient safety data under a law that protects data in this system. Representatives from another patient safety reporting system told us that communicating information about available legal protections can be particularly important for systems that collect data from providers in multiple states, because the legal protections for providers and patient safety data vary from state to state. For example, representatives from two patient safety reporting systems with users in multiple states said their systems provided customized legal information for providers based on the state confidentiality laws that applied to each provider's location. A representative from one of these systems also said that the legal information the system offered helped providers understand what types of data to submit and encouraged them to submit it.

Data collection tools intended to standardize the data providers submit. Representatives from all five systems told us they had developed

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[2]Literature in the field of patient safety identified learning from a patient safety event, rather than blaming individuals for the event, as a key to supporting a culture of safety. According to the literature, a culture of safety holds people accountable for any deliberately unsafe acts in the health care they deliver but does not blame them for patient safety events that may have causes in the ways, or system, through which health care is delivered.

tools intended to standardize the data providers submit to their patient safety databases. For some systems these tools include common formats and computer systems.[3] Some of the representatives explained that standardizing the information providers submit helps ensure that patient safety events, especially events involving clinical terms, are classified in the same way.[4] Some representatives also said that if a system did not define clinical terms for providers, providers may define events differently, which can limit the system's ability to analyze submitted patient safety data. Furthermore, the representatives said, standardizing terms increased the value of the data as it is aggregated, as well as any resulting analyses. Representatives from all five systems said the ability to collect and aggregate standardized patient safety data allowed them to identify patterns in patient safety events, which they believed enabled their systems to suggest ways to improve patient safety.

Some system representatives said that standardizing the way providers submit patient safety data allowed them to streamline the data collection process for providers. Some representatives said they designed their data collection protocols to allow providers to fulfill additional reporting requirements related to accreditation or quality improvement functions, such as submitting data regarding certain patient safety events to the Joint Commission.[5] Representatives from one system said that their systems did this to make collecting and submitting patient safety data more efficient for providers and thereby increase the likelihood that providers would submit such data to the patient safety reporting system. In another example, one system built a feature into its computer program that allowed providers to transfer data directly from providers' in-house databases to the patient safety data collection system, a data collection

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[3]Common formats are one type of data collection protocol that can include a standardized summary of the necessary information to be submitted, common and consistent definitions, and a standardized computer interface for submitting data to the collection system.

[4]To ensure that providers are able to correctly use the data collection protocols that systems provide to standardize data, representatives from all the systems said that they offer training or technical support to providers. System representatives said they used a range of training, including workshops on collecting patient safety data, written materials describing how to conduct root causes analyses of events, and Web-based reference guides for using a patient safety data collection system.

[5]The Joint Commission is a nonprofit organization that develops standards for quality and safety in health care and accredits hospitals and other health care providers.

method system representatives said accounted for approximately
40 percent of all data received from providers.

Data analyses that produce actionable feedback. Representatives
from all five patient safety reporting systems told us that their systems
analyzed submitted data to develop actionable steps providers could
implement to improve patient safety. According to the representatives,
their systems aggregated data from provider submissions and used these
data for both quantitative analyses, such as trend or frequency analyses,
and qualitative analyses, which examine narrative data to determine
whether there were any common themes across events. Representatives
from all five systems said they used both qualitative and quantitative
analyses because neither method alone was completely sufficient to
develop improvements to patient safety. For example, one system's
representatives said they conducted qualitative analyses such as using a
computer program to analyze and group the narrative data providers
submitted to learn about the factors that contributed to patient safety
events. The same representatives explained that their system also
conducted quantitative analyses such as trend analyses on events to see
how often they occur.

Representatives from all the systems said they used various methods to
encourage providers to implement the improvements to patient safety the
systems helped develop. Examples of methods they used included sending
an e-mail from the system when new content was published on the
system's Web site, hosting Web conferences, and publishing analyses in
trade or scholarly publications. All the representatives said their systems
collaborated with other organizations to increase the likelihood that the
improvements they developed were implemented. For example, one
system worked with a statewide coalition of organizations in the quality
improvement field to encourage providers to implement the patient safety
improvements the system developed.

Appendix II: Selected Statutory Requirements for Listing of Patient Safety Organizations

A PSO must certify that it has policies and procedures in place to perform each of the following patient safety 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.

A PSO must certify that upon being listed, it will comply with the following criteria:

1. The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.
2. The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.
3. The entity, within each 24-month period that begins after the date of the initial listing, has bona fide contracts, each of a reasonable period of time, with more than 1 provider for the purpose of receiving and reviewing patient safety work product.
4. The entity is not, and is not a component of, a health insurance issuer.
5. The entity shall fully disclose—(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and (ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.
6. To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.
7. The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

Additional Criteria for Component Organizations

8. The entity maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.
9. The entity does not make an unauthorized disclosure under this part of patient safety work product to the rest of the organization in breach of confidentiality.
10. The mission of the entity does not create a conflict of interest with the rest of the organization.

Source: The Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact:	Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov
Staff Acknowledgments:	In addition to the contact named above, William Simerl, Assistant Director; Eric R. Anderson; Eleanor M. Cambridge; Krister Friday; Kevin Milne; and Andrea E. Richardson made key contributions to this report.