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Adverse Event Reporting in Massachusetts and Other States: Status and Trends in 2014

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Acknowledgements

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Introduction

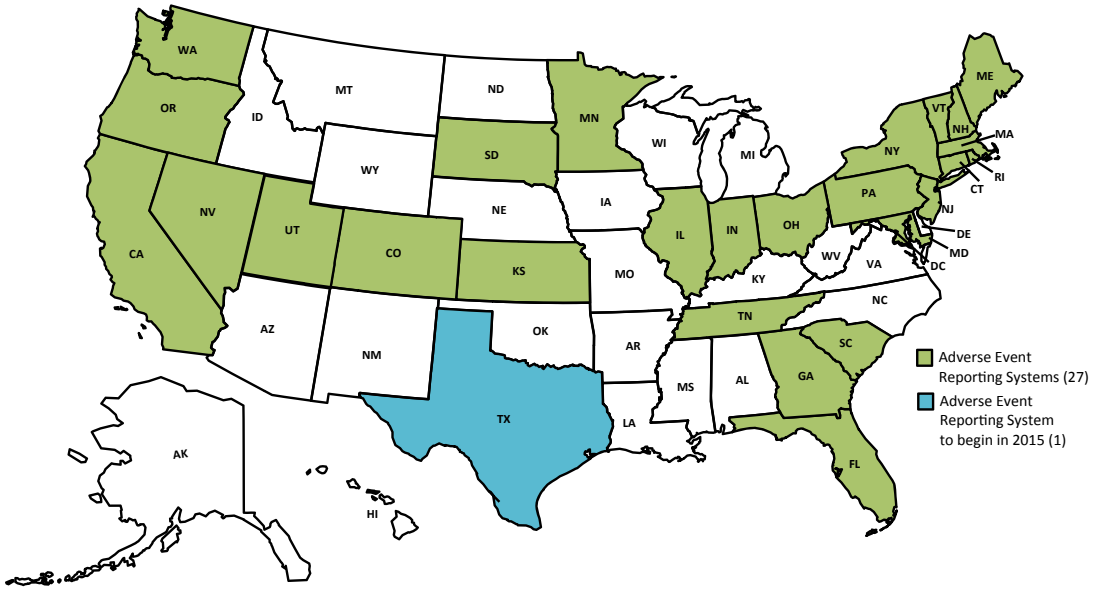
In 2014, The National Academy for State Health Policy (NASHP) surveyed all 50 states to develop insight into the nation's monitoring, regulation and promotion of patient safety, with a particular focus on adverse event reporting systems. For the purposes of this research, state adverse event reporting systems are defined as a system authorized by, and usually operated by, state government to collect reports from hospitals (and in some cases other types of facilities such as ambulatory surgical centers) about adverse events, with the intent of improving patient safety.[1]

As of November 2014, Massachusetts is one of 26 states and the District of Columbia with adverse event reporting systems. An official from each state with an adverse event reporting system completed NASHP's online survey, for a total of 28[2] responses. NASHP also conducted key informant interviews with stakeholders in Massachusetts and four other states (Maryland, New York, Oregon and Pennsylvania) to explore innovations in patient safety, successes and challenges, and integration of adverse event reporting with broader state efforts to improve patient safety and quality of care.

The following sections describe the results of the 2014 survey, highlighting salient state examples and providing a comparative analysis to Massachusetts.

In its 1999 report, the Institute of Medicine (IOM) called for a nationwide, mandatory reporting system for state governments to collect standardized information about adverse medical events[3] resulting in death and serious harm.[4] The IOM's call for this national system has not been heeded. Nevertheless, since that report, some states have made significant progress in standardizing the types of events to report, improving follow up with health care providers after an event has occurred, and broadening the scope of facilities from which they collect data. Of the 26 states and the District of Columbia with adverse event reporting systems (See Figure 1), all are mandatory except for Oregon.[5]

Figure 1: Adverse Event Reporting Systems, November 2014



Reporting Systems in Massachusetts

Of the 26 states and the District of Colombia that report, Massachusetts is the only one that requires health care facilities to report adverse events to two agencies. Both the Massachusetts Department of Public Health's Bureau of Healthcare Safety and Quality as well as the Board of Registration in Medicine (BORIM) collect data from hospitals and other facilities, yet interaction and information sharing between the two entities is limited. The argument could be made that both systems are useful and serve different purposes in their reporting of either confidential or public information, yet there is agreement that Massachusetts could more effectively leverage information from both entities. (Table 1 presents a detailed look at the two Massachusetts systems).

- The Department of Public Health's Bureau of Healthcare Safety and Quality administers one mandatory reporting system for the reporting of incidents, called Serious Reportable Events (SREs),[6] that drastically affect the health and safety of patients in hospitals and ambulatory surgical centers.[7] The department began collecting information about adverse events from hospitals in the 1980s. Reporting guidelines have been revised multiple times; the Department of Public Health adopted the National Quality Forum's (NQF) definitions for adverse events

(described on page 5) in 2008. Today, the reporting system is intended to serve as a quality and safety indicator tool, as well as to inform education and practice, and foster transparency.

- BORIM is the state's licensing authority for physicians. In 1986, intending it to be an oversight system for these institutions' patient safety programs, the legislature expanded BORIM's authority to the health care institutions in which physicians practice medicine. Under this legislation, hospitals and nursing homes were required to develop and share a plan for ensuring patient safety, known as the Patient Care Assessment Program.[8] They also must report "major incidents" to BORIM. Currently, BORIM's Safety and Quality Division administers the agency's reporting system that requires hospitals, ambulatory surgical centers, and ambulatory clinics to report unexpected serious patient outcomes, also known as Safety and Quality Reviews (SQRs).[9] Nursing homes are no longer required to report events to BORIM.

Table 1: Comparing Two Systems that Collect Adverse Events in Massachusetts

	Massachusetts Department of Public Health	Massachusetts Board of Registration in Medicine
Facilities Required to Report Adverse Events	Hospitals, ambulatory surgical centers	Hospitals, ambulatory surgical centers, and ambulatory clinics
Source of Reportable Event Lists Used in Adverse Event Reporting Systems	National Quality Forum (NQF) list of events[i]	State-specific list of events
Process for Collecting Reporting Data	Electronic	Manual (data are submitted on paper and entered into a database)
Type of Data Reported Publicly	Facility-specific information	Aggregate data (number of events)
Frequency of Public Reporting	Annually	Annually
Feedback Loop for Sharing Information with Facilities that Report Events	Analysis provided to individual facilities about their incidents	Analysis provided to individual facilities about their incidents, aggregate information across facilities shared with all providers, and additional information shared through newsletters and advisories
Root Cause Analysis (RCA) Requirements	RCA required, along with preventability analysis and corrective action plan.	Description of the event, internal review findings and actions plans required; RCA accepted if it contains information to assure the event underwent a thorough review and facility identified all opportunities for improvement
Corrective Action Plan (CAP) Requirements	Requires a CAP	Events reported are not always determined preventable; in those cases a CAP may not be required.
Reporting System Funding Source	State dedicated funding stream	Agency general operating funds

[i]Only acute and non-acute hospitals use the NQF list.

These two systems could potentially be informed by Pennsylvania, where data also are used by more than one regulatory agency. However, in Pennsylvania, health care facilities provide information about their incidents only once, and the reporting system bifurcates the data to ensure appropriate agencies receive it. Depending on the nature of the adverse event, the system automatically sends a report to the Patient Safety Authority (which administers the reporting system), the Department of Health, or both. In this way, both agencies are able to use the information as appropriate without adding to the providers' reporting burden.

The following sections of this report provide information about the two reporting systems in Massachusetts as well as comparisons with other states.

Facilities that Report Events

In 2014, all reporting systems – including both in Massachusetts – require event reporting from hospitals. The Massachusetts Department of Public Health collects SRE reports from hospitals and ambulatory surgical centers.[10] Hospitals must notify the department of an SRE within seven days of discovery of the error; sooner if one of a number of other specified incidents have occurred, including an unanticipated death, fire, suicide, or serious criminal act.

BORIM requires hospitals, ambulatory surgical centers and ambulatory clinics to submit reports. The reports include a description of the event, the internal review findings and action plans identifying all opportunities for improvement. On average, 60 percent of these reports do not meet the definition of a serious reportable event, and all reported information is completely confidential. In addition to quarterly SQR reports, facilities submit semi-annual reports to BORIM that include the description of patient safety activities and initiatives, the data they are collecting, and how they are responding to trends and patient complaints.

Only six states, California, Georgia, Maryland, Ohio, Rhode Island and Vermont, require reports solely from hospitals.[11] In addition to the Massachusetts Department of Public Health system, three other systems, Colorado, the District of Columbia, and Tennessee, collect reports from the following facilities: hospitals, ambulatory surgical centers, long term care centers, ambulatory clinics, and home care providers. Additionally, 16 state systems[12] collect reporting information from other facilities such as abortion clinics, birthing centers, substance abuse or dependency facilities, renal disease facilities, clinical labs or pharmacies.[13]

Reportable Events

In 2002, NQF published a recommended list of standardized reportable events as the basis of a national, state-based reporting system in *Serious Reportable Events in Healthcare: A Consensus Report*.[14] The list was updated in 2006 and again in 2011. National entities continue to utilize or adapt the list to shed light on serious reportable events and help prevent their reoccurrence.[15]

The 2011 update includes 29 adverse events that are unambiguous, largely preventable, and serious, as well as adverse, indicative of a problem in a healthcare setting's safety systems, or important for public credibility or accountability. [16] These events are organized into seven categories; six relate to the provision of care, such as surgical or invasive procedure, product or device, patient protection, care management, environmental and radiologic, and one is for potential criminal events (see text box).[17] Twenty-five of the 29 endorsed events were updated in NQF's 2011 report. States can adopt (or adapt) the NQF list of events in their reporting systems or develop a state-specific list of events. More than a decade after NQF's report, 15 states have adopted or adapted the organization's list of adverse events for their reporting sytems.

NQF Serious Reportable Events- 2011 Update

1. Surgical or Invasive Procedure Events

- Surgery or other invasive procedure performed on the wrong site
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient

2. Product or Device Events

- Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by healthcare setting
- Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

3. Patient Protection Events

- Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
- Patient death or serious injury associated with patient elopement (disappearance)
- Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

4. Care Management Events

- Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious injury associated with unsafe administration of blood products
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Patient death or serious injury associated with a fall while being cared for in a healthcare setting
- Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
- Artificial insemination with the wrong donor sperm or wrong egg
- Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

5. Environmental Events

- Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
- Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances
- Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting
- Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

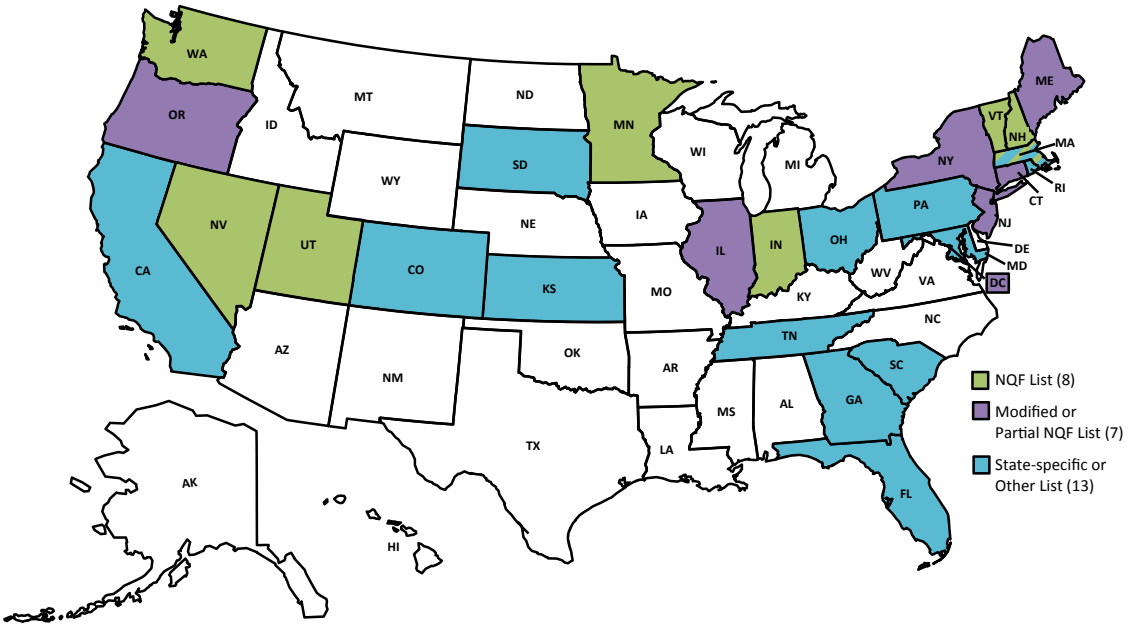
6. Radiologic Events

- Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

7. Potential Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient/resident of any age
- Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
- Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting

Figure 2: Source of Reportable Event Lists Used in Adverse Event Reporting Systems



Note: Facilities in Maryland use a state-defined list to report adverse events, however the state uses a modified NQF list to classify events after they are reported.

As outlined in Figure 2:

- In 2014, the Massachusetts Department of Public Health system has adopted the NQF list for acute and non-acute hospitals and surgical centers. Seven other state reporting systems have adopted the NQF list.[19]
- BORIM, along with 11 other systems, uses a state-specific list of reportable events.[20]
- Seven systems use a modified or partial NQF list.[21]
- In all, 13 reporting systems use a non-NQF list.[22] In addition to the 12 systems using a state-specific list of reportable events, one state, Ohio, uses the Agency for Healthcare Research and Quality's (AHRQ) patient safety indicators for its list of reportable events.

Several states require reporting of some events from the NQF list, as well as additional incidents. In Oregon where the reporting system is voluntary, for example, reports of criminal events on the NQF list are not collected. The state has also added categories of events that were commonly submitted as "other" in the past. New York uses a partial list of NQF events along with seven state-specific events. The District of Columbia uses 28 NQF serious reportable events as well as central line-associated bloodstream infections in intensive care units as a participant in the Centers for Disease Control and Prevention (CDC)'s National Healthcare Safety Network.[23]

Due to differences in reporting protocols and enforcement, the number of reports states receive each year ranges from hundreds to thousands. Pennsylvania, which requires reporting on the most extensive list of events, including events that do not cause harm to patients, receives hundreds of thousands of reports. BORIM received 983 reports of SQRs in 2013 and the Massachusetts Department of Public Health received 959 SRE reports from hospitals (753 acute care and 206 non-acute care). The number of reported events

varies from state-to-state based on how events are defined, the number of facilities and beds in the state, the number of procedures performed, and compliance and enforcement of reporting requirements.

As a result, the number of events reported is not a valid indicator of the true extent of patient harm. Additionally, many officials believe that adverse events are significantly underreported.[24] Providers may fail to report events for a number of reasons, including the fear of publicity or punitive actions, lack of knowledge of the event, or misunderstandings about the reporting system.[25] Despite this reality, system officials find reported data to be useful (see "Data Use" section).

Reporting Mechanisms

Technology has evolved over the years, allowing state reporting systems to increasingly become electronic. Fourteen years ago, only one state could receive reports electronically.[26] In 2014, 22 of the 28 systems, including the one administered by the Massachusetts Department of Public Health, collect data electronically. In Utah, facilities enter data into a web-based reporting portal. The BORIM system is one of five state systems that only collects data manually, while seven states accept both manual and electronic data.[27] For example, in Washington State, facilities mostly report events electronically, but they provide Root Cause Analyses (RCAs) in paper format.

Data Use

The use of reported adverse event data varies among states. State agencies hold individual facilities accountable for correcting problems that led to errors; share information about common errors and best practices in prevention across facilities; and inform policy makers, consumers, and other stakeholders about patient safety issues in order to motivate change or guide decision making.[28] Both systems in Massachusetts, as well as 11 other states, report using data to assess facility-level changes and inform provider or facility education. In order to use data in these ways, states determine whether or not to publicly disseminate reporting system data, the kind(s) of data to disseminate, and the stakeholders with whom to share.

Public Reporting

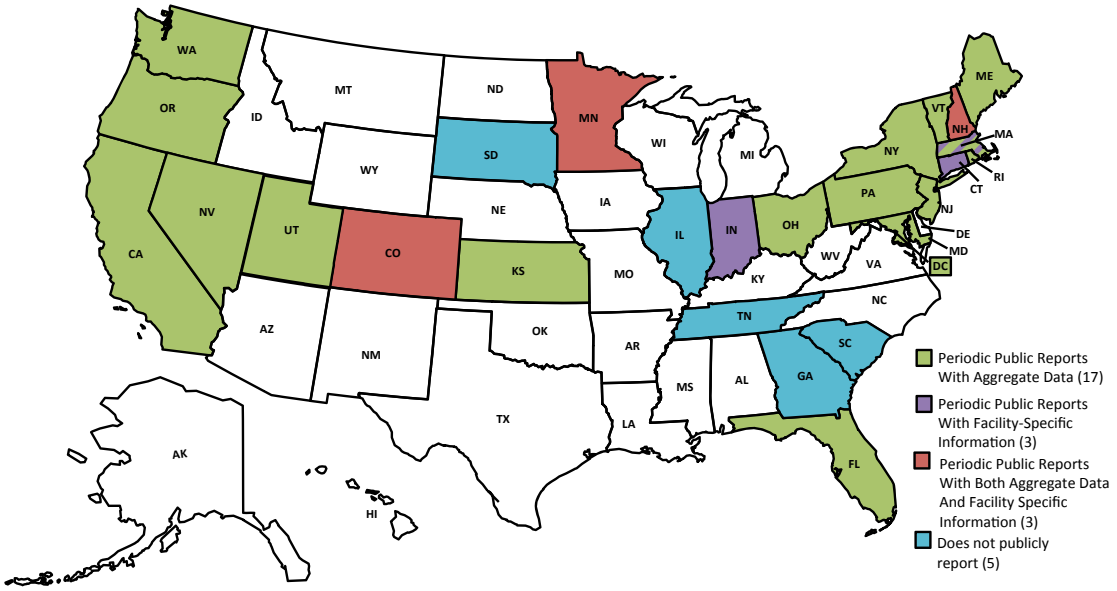
The IOM called for public reporting in state systems and emphasized transparency as one of 10 principles that should guide the redesign of the health care system.[29] Public reporting is one mechanism that states use to disseminate data to drive quality improvements in health care. It can promote learning among both providers and consumers regarding safety risks, and can advance accountability of individual providers and organizations for safety.[30] States can report facility-specific data, or data that is aggregated across facilities, which allows them to assess the patient safety performance of a facility or the state as a whole. By aggregating data across facilities, states have a greater number of events for analysis and may be able to identify root causes that cannot be identified by an individual facility.

As outlined in Figure 3 (next page):

- BORIM issues periodic public reports with only aggregate data, as do 15 other states and the District of Columbia.[31,32] However, compared to the other systems' reports, which generally include trends in data and events, BORIM shares a narrower scope of information-only the number of events reported.

- The Massachusetts Department of Public Health system releases periodic public reports with only facility-specific information. Two additional states[33] issue periodic public reports that contain facility-specific information without aggregating the data. Three systems[34] publicly release both aggregate data and facility-specific information.
- Five states do not report data to the public.[35]

Figure 3: System Information Sharing with the Public, 2014



Notes: BORIM releases aggregate data, while the Massachusetts Department of Public Health system releases facility-specific information without aggregating the data. Nevada has the authority to publish facility-specific data, but has yet to do so. A draft report is undergoing revision, and therefore remains unpublished.

Georgia, South Carolina and South Dakota do not publicly report data, but will provide incident-specific information upon request. Tennessee presents its data to providers in an aggregate form, but no longer reports publicly. Illinois also does not report publicly in 2014.

Most state systems (15 in 2014) publicly report the information they collect from providers on an annual basis.[36] Six state systems[37] release the adverse event data more frequently—on a weekly, monthly, quarterly, or semi-annual schedule. In Massachusetts, both BORIM and the Department of Public Health publish data on an annual basis, though, as noted earlier, BORIM shares only the aggregate number of reports received from facilities. All facility-specific events reported to the Department of Public Health are in the public domain, whereas all information reported to BORIM is completely confidential. The Department of Public Health is also required to release certain information about a specific event upon request.

Colorado issues monthly data reports including both the type of event that occurred and the types of facilities reporting, while also publishing an occurrence summary report online each week. Oregon generates topical reports that may include data from facilities to provide context. Washington State compiles and posts notifications of adverse events quarterly on its website.

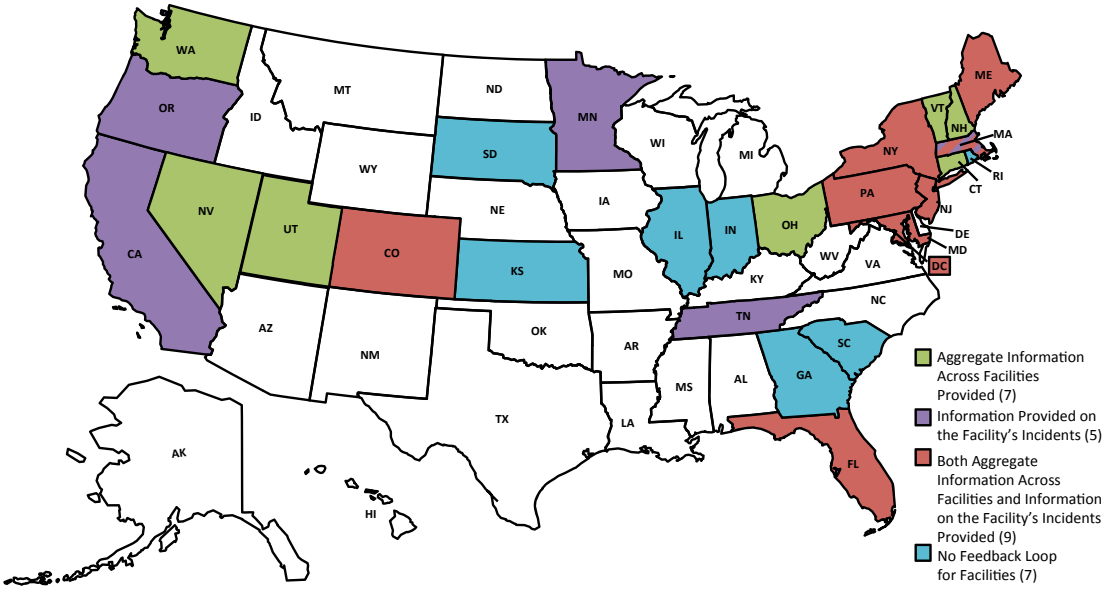
Sharing Information with Facilities

States provide feedback to facilities through a variety of channels such as: patient safety webinars to train providers; telephone and electronic messaging systems; newsletters and advisories; and periodic in-person meetings.

In 2014, the majority of state systems share information with providers and facilities (See Figure 4). The information most often takes one of two forms: providers receive aggregated information about events reported to the state across all facilities, or they are given data that identifies the number of incidents at each hospital or facility that reports to the state.

- The Massachusetts Department of Public Health shares facility-specific information with individual facilities about their incidents. BORIM shares both aggregate and facility-specific information.
- Sixteen total systems share aggregate information across facilities.[38]
- In addition to the two Massachusetts systems, 12 others share facility-specific incident information with facilities about their incidents.[39]
- Seven states do not have a feedback loop for sharing information with providers.[40]

Figure 4: System Information Sharing with Facilities, 2014



Many states, including Massachusetts, want adverse event reporting data to contribute to patient safety education and training more broadly. BORIM shares information with facilities about preventing adverse events through newsletters and advisories; topics are selected based on reports received. BORIM has also convened expert panels on safety topics and published the findings.

Similarly, Pennsylvania uses de-identified event information in its peer reviewed *Pennsylvania Patient Safety Advisory* as one vehicle to share event data with facilities, promote learning, and prevent event reoccurrence. The *Advisory* is a quarterly journal containing articles about events that took place in Pennsylvania healthcare facilities. Each article includes guidance about measures facilities can adopt

to improve patient safety. Individual facilities in Pennsylvania are also able to use the state's system to view and analyze their own data. Aggregate comparison information also is incorporated in annual public reports and used to further support education efforts.

Oregon has a monthly newsletter that includes a standard "action alert," sharing important lessons learned from adverse event information. Trends identified in the data reported to the state inform the newsletter topics so they are relevant and timely. New York and the District of Columbia offer periodic webinars and educational sessions on relevant patient safety topics, and Tennessee conducts annual trainings for providers. Colorado works directly with facilities to support effective self-investigations and corrective actions where needed.

Six systems[41] provide customized feedback to facilities by phone and the Internet based on the data received. In Oregon, Patient Safety Consultants (PSCs) review submitted reports and provide individualized feedback via an online reporting tool. Feedback is tailored to the needs of each participant and may include links to quality improvement resources, suggestions for how to improve investigation procedures, or support for their analyses. In addition, when a report is submitted with unclear or inadequate information, a PSC will often call the reporting contact to ask additional questions, and may provide feedback at that time as well. Utah also clarifies any questions through phone conversations. Similarly, in New York, clinical reviewers use phone conversations and electronic messaging systems to provide feedback.[42] In Maryland and the District of Columbia, clinical electronic alerts are shared with providers when warranted by specific events.

Two states provide feedback to facilities through committees and meetings. In Connecticut, the conduits are a statewide Quality of Health Care Advisory Committee, a subcommittee on best practices and adverse events, and conversations with the state hospital association. New Hampshire also provides feedback by convening quarterly meetings of providers.

Review Processes

States have processes in place for reviewing adverse event information submitted to them. For example, they may require a facility to conduct its own Root Cause Analysis (RCA), the incident may be subjected to a clinical review, or the state's reporting authority may perform an on-site investigation.

An RCA is a structured method utilized to analyze serious adverse events to identify deeper underlying systemic problems that increase the likelihood of errors, rather than focusing on mistakes that may have been made by individuals.[43] Done well, an RCA can help prevent recurrences by identifying what happened, why it happened, and what steps can be taken to prevent a similar event from happening again. This information can help health care providers make internal process improvements and aids the states' understanding of underlying causes of patient harm to potentially reduce recurrence.

A number of states also require their providers to submit a corrective action plan (CAP) in the aftermath of an adverse event. A CAP is a step-by-step plan of action developed to achieve targeted outcomes for resolution of identified errors.[44]

- In 2014, the Massachusetts Department of Public Health required both an RCA and a CAP. BORIM has provisions related to RCAs and CAPs even though it does not explicitly require them.
- In all, 20 state systems require an RCA,[45] 19 states require a CAP,[46] and 15 states require both.[47]
- Sixteen[48] states reported that they conduct clinical reviews, on-site investigations, and in some cases, surveillance.[49]

- Four additional systems[50] have provisions related to RCAs or CAPs even though they do not explicitly require them.

BORIM requires health care facilities to submit a description of the event, internal review findings, and actions plans. BORIM will accept RCAs if they contain sufficient information assuring that the event underwent a thorough multidisciplinary review identifying all opportunities for improvement. BORIM may not require a CAP for all events; however, it tries to spotlight lessons learned and identify opportunities for improvement regardless of whether an event is preventable.

RCA mechanisms take a number of different forms across the country. In Indiana, submission of an RCA report is part of the licensing and certification quality assurance requirements rather than the reporting requirements. In the District of Columbia, an RCA is not required but can be submitted to officials for help with analysis and feedback. Colorado also does not require RCA submission but asks that facilities conduct an RCA and include the outcomes as part of their final reports to the state. All occurrence reports in Colorado include an investigation, and corrective actions are subject to review during a state on-site survey. In Utah, only the findings of the RCA need to be reported. Patient Safety Consultants in Oregon review RCAs, identify opportunities for process improvement, and provide periodic RCA training and support. Washington requires facilities to submit RCAs but the state does not review them due to funding losses in 2011.

CAPs also play a role in trying to reduce the overall incidence of patient harm. South Carolina only requires a CAP if the reported incident is determined to need investigation that leads to a citation. In Florida, reports of an error submitted must include a CAP and information about all corrective actions taken. State reporting officials use the information to conduct a review of the incident and determine whether a survey of the facility is warranted. In New York, RCAs are required for the most serious events. Rather than submit a separate CAP report for these events, facilities must submit a detailed risk reduction strategy that includes effectiveness measures for monitoring their own adherence to the plan as part of their RCA. In Oregon, CAPs are called "Action Plans" and each must identify at least one cause, but may include up to five, and indicate the "root" causes. Each cause must have an associated "Action Plan". In the District of Columbia as with an RCA, if a CAP is submitted, it is analyzed and feedback submitted to the facility.

Provider Input on Adverse Event Reporting Systems

Provider input has helped a number of states revise or create tools to better meet the needs of participants while improving patient safety across the state. Thirteen states indicated that they make use of provider feedback to help streamline reporting processes and simplify reporting for facilities.[51]

In Massachusetts, both the Department of Public Health and BORIM noted that a number of proposed system improvements based on provider input are pending, including expanded field options in the online entry system and clarification of reporting requirements. Templates that make it easier to enter data for specific SREs have also been proposed.

The Patient Safety Act requires streamlined reporting of safety-related data to the federal government.[52] Minnesota and District of Columbia officials have updated their online systems to improve reporting compliance. South Dakota updated its reporting intake forms and hired an additional staff member to help providers meet their reporting requirements. While New York's reporting system has always been statewide, in 2011 the management of the program changed from a regional to centralized process. This change has provided a more standardized approach to the management of the program, and provider

feedback has been positive. Oregon developed an online reporting system, revised response options in the reporting system, and implemented a program to recognize its leading reporters. Utah is currently revising its system, moving away from an approach that focused on sentinel – or most serious – events to a broader patient safety surveillance and improvement program. The new approach requires greater public transparency for accountability and a learning collaborative to improve provider interaction regarding common safety issues.

In Massachusetts, as in many states, the relationship between the agencies that administer the reporting system and the provider community is complicated. Many providers want to engage in patient safety initiatives and are committed to providing the highest quality care to their patients, but they have limited time and capacity. Other priorities likely absorb resources, and state officials may need to offer incentives, or include providers in pilot projects that demonstrate small successes and keep them engaged. State officials believe they have made significant efforts to remove the stigma of reporting events, yet there are providers who remain hesitant to report. This issue can be more challenging under Massachusetts' dual reporting systems; due to the confidentiality protocols at BORIM, some providers may only report an event there instead of to both agencies, as is required. There are some safeguards in place to help prevent this however; if a health care facility has not indicated that a reported event is an SRE on BORIM's form but BORIM believes the event may meet requirements for SRE reporting, it advises the health care facility to contact the public health department for clarification on whether the event should also be reported as an SRE. Facilities are expected to be compliant with all reporting mandates.

Implications of Adverse Reporting Systems in States

Adverse event reporting systems can contribute to quality improvement and delivery system transformation initiatives in states through cross-agency partnerships and collaborations.

To better understand these implications, NASHP's survey asked system officials about the impact of their systems, the integration of systems with other state initiatives, their potential relationships with Patient Safety Organizations, and system funding.

Impact of Adverse Event Reporting Systems

Measuring the impact of an adverse event reporting system is a complicated undertaking. For example, it is hard to quantify events that may have been prevented through improved provider education or new initiatives. In addition, a low number of adverse events reported to the state reflects only reporting activity and is not necessarily indicative of the true scope of these incidents. Despite the limitations of data reported to states, most officials (23) indicated that their systems have fostered communication, guided provider training, enabled internal agency (or facility) tracking or trending of patient safety, and/or brought about greater transparency and awareness of patient safety. States use data analysis, facility or provider surveys, provider or facility training, and more rarely, formal evaluations to try to better understand how their reporting systems affect safety.

Some states gauge the impact of their adverse event reporting systems by analyzing trends and patterns in reported data. These efforts can help a state demonstrate improvements in patient safety while also tracking trends of non-compliant facilities and services. For example, BORIM uses its data to assess the internal quality and patient safety systems at health care facilities, including systems for medical staff credentialing. When BORIM identifies concerns, it works directly with health care facility boards and administrative and medical staff leadership to monitor system improvements.

Other states use their reporting systems to contribute to patient safety education and training. BORIM leads education efforts for facilities, highlighting lessons learned and identifying opportunities for improvement, regardless of whether a reported event is preventable. In the case of the Massachusetts Department of Public Health, officials acknowledge the inherent tension of being a regulatory entity while also encouraging learning and fostering a safer environment in health care facilities, but continue to spearhead efforts to improve patient safety. In Maine, officials respond to requests for technical assistance and education from facilities. Pennsylvania communicates information to facilities through its *Pennsylvania Patient Safety Advisory* and other modalities, and develops statewide trainings on patient safety topics for thousands of providers. In Maryland, hospitals changed practices after receiving clinical alerts from the state about adverse events.

Oregon measures the impact of its reporting system in three ways: quantity, whether participants are reporting; quality, whether participants identify the root cause in investigations and system-level prevention strategies in their action plans; and timeliness, whether participants report in a reasonable amount of time of the date of event discovery. Aggregate data and analysis provide insight into areas where participants in Oregon may need additional support, and help guide the development of appropriate tools and resources to address those issues. Similarly, Maryland and the District of Columbia analyze reported data and measure impact by looking at specific trends such as decreases in the number of deaths from falls, while Pennsylvania uses system data to support and inform collaboratives aimed at reducing significant patient safety events.

Surveys have provided valuable data and insight on the impact of state adverse event reporting systems. Florida measures impact through an annual hospital risk management survey, which includes a review of a sample of adverse events, as well as through internal reports for tracking and trending data. The survey data allow Florida to assess facility response for quality improvement purposes. South Dakota also measures impact through a survey process and discussions with facilities.

Perhaps due to limited resources and staffing, only three states have pursued formal evaluations of their reporting systems; two include surveys. Pennsylvania surveys hospital facilities each year on the ease of system use; the survey also inquires whether facilities have taken actions based on articles published in the *Pennsylvania Patient Safety Advisory*. Pennsylvania uses this information to make changes in the reporting system and also includes the information in annual reports, which are publicly available. Results of an evaluation survey in Minnesota demonstrated a heightened awareness of patient safety in facilities and a feeling of increased safety among providers compared to 10 years ago.[53] California is in the process of conducting an evaluation of its reporting system, with results expected in 2015.

Overall, nine states[54] reported increased levels of provider and facility awareness of patient safety, which can lead to the identification of causal factors associated with adverse events, and ultimately, to an opportunity for patient safety improvement. Utah and Maine specifically noted that their reporting systems have raised facility awareness of adverse events and helped foster facility trust, resulting in regular communication and an increased willingness among facilities to disclose adverse events. Five states[55] noted that the requirement to report to a system has facilitated internal data tracking and trending by the state or facilities. Minnesota and New Hampshire indicated that there is increased transparency about adverse events as a result of their system; five other states[56] reported that their systems have helped guide facilities in identifying or implementing improvement strategies centered on safety.

Integration with Other State Initiatives

To help assess impact, NASHP asked reporting system officials to identify how their reporting systems align with other patient safety, quality improvement, and delivery system transformation initiatives within

their states. Adverse event reporting often overlaps with other patient safety efforts (including initiatives led by Patient Safety Organizations, described in the next section), making partnerships and collaboration across agencies and with other organizations an important strategy for improving patient safety. At the same time, specific examples of collaboration or integration that demonstrate the importance of patient safety as part of quality improvement or delivery system transformation initiatives are rare.

Oregon tries to align its definitions of adverse events with national agencies such as AHRQ (i.e. Common Formats[57]) and CDC's National Healthcare Safety Network. This is designed to improve coordination with other state public health priorities, such as mandatory infection reporting to the Oregon Department of Public Health, as well as various quality assurance and performance improvement and accreditation programs. By aligning definitions with other state efforts, Oregon aims to decrease the reporting burden on facilities and help them coordinate quality improvement efforts that target some of the same goals or metrics (e.g., falls prevention). In New York, adverse event data are shared within the health department, notably with radiation protections, infectious disease, and maternal mortality reduction programs.

The reporting system in Pennsylvania supports numerous collaboratives across the state including the Partnership for Patients Hospital Engagement Networks.[58] Reporting system officials in Maryland work with the Maryland Patient Safety Center[59] on conferences and efforts such as the Maryland Hospital Hand Hygiene Collaborative[60] and the SAFE from FALLS Initiative.[61] They also work across state agencies with the Maryland Health Services Cost Review Commission and the Maryland Health Care Commission on other quality initiatives.

In Indiana, the reporting system is integrated with the health care facility licensing and Medicare/Medicaid certification program. Similarly, California is incorporating its adverse events, patient safety licensing activities, and medication error reduction surveys into one comprehensive licensing survey. Aggregate patient safety data are integrated into hospital community report cards in Vermont.[62]

Nonpayment policies,[63] community health reports, and similar activities are often part of broad state or federally-led health care system transformation efforts to improve quality, lower costs and improve health. Initiatives such as the State Innovation Model (SIM)[64] and Delivery System Reform Incentive Payment[65] programs are much broader than patient safety but present concrete opportunities to link quality and safety. However most survey respondents did not explicitly indicate if or how their states had integrated patient safety into these specific health care transformation efforts. A few respondents noted that their reporting system goals are in alignment with broad patient safety or quality improvement initiatives, but did not indicate how their states specifically aligned the efforts. In other words, despite complementary goals, adverse event reporting systems overall seem to stand alone from states' broad quality improvement, cost containment, and other delivery system reforms.[66]

Patient Safety Organization Reporting Relationships and Requirements

In response to the IOM's 1999 report, Congress developed and enacted the Patient Safety and Quality Improvement Act of 2005. The Act offered certain privilege and confidentiality protections for providers who work with federally-listed Patient Safety Organizations (PSOs),[67] and was intended to promote shared learning to enhance quality and safety nationally.[68] The final Patient Safety Rule was adopted in November 2008 and became effective in January 2009. The Affordable Care Act (ACA) brought additional changes by requiring hospitals with more than 50 beds that wish to contract with Qualified Health Plans in health insurance marketplaces to work with PSOs. In March 2014, the Centers for Medicare and Medicaid Services adopted a proposal that postpones this requirement until 2017.

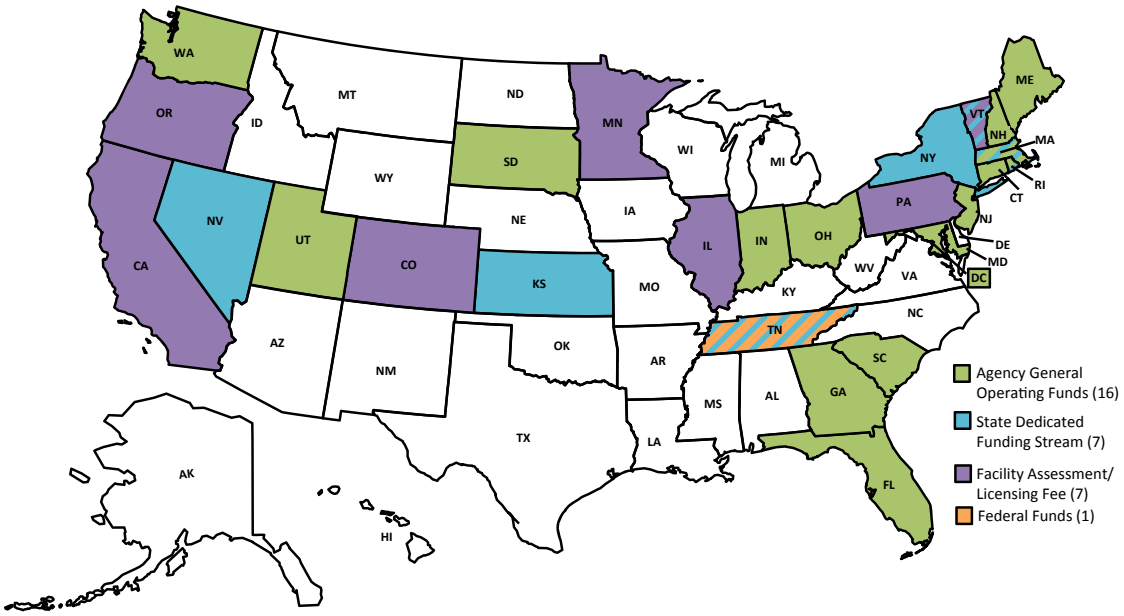
As a result of these upcoming PSO reporting relationships and requirements, a few states are considering changes to their reporting systems. BORIM, along with Connecticut, the District of Columbia, and Indiana are reviewing reporting requirements and evaluating potential changes to their systems. New York is exploring formats such as those established by AHRQ's Common Formats to improve the collection of standardized information to more easily share data with researchers and providers. However, most states, including reporting system officials at the Massachusetts Department of Public Health, are not intending to change their reporting requirements.[69] Overall, the rise of PSOs in the last five years has yet to have a large effect on Massachusetts' agencies.

System Funding

Officials draw from a variety of funding sources to operate their reporting systems (see Figure 5). The majority of systems are funded through agency general operating funds, but several states are also supported through facility assessment and licensing fees and dedicated state funding streams.

- BORIM and 15 other systems use agency general operating funds to finance their reporting system operations.[70]
- The Massachusetts Department of Public Health and six other systems are funded through a dedicated state funding stream. [71]
- Seven states are supported by a facility assessment or licensing fee.[72]
- One state, Tennessee, receives a combination of federal and state funding support.

Figure 5: Funding Sources for Adverse Event Reporting Systems, June 2014



Conclusion

Recent survey data demonstrate continued state commitment to tracking adverse events and using reported data to improve patient safety. Although the IOM call for a national system of mandatory reporting has not been realized, just over half of states have an adverse event reporting system for a total of 28 adverse event reporting systems in 26 states and the District of Columbia. Numerous states have modified their systems in the past several years with others in the process of identifying or implementing changes.

Key findings for Massachusetts include:

- Twenty-six states and the District of Columbia have reporting systems to monitor occurrence of adverse medical events, a number that has not changed significantly since NASHP's 2007 survey. Momentum to establish a nationwide, mandatory reporting system for state governments to collect standardized information about adverse events - fueled by the seminal IOM report, *To Err is Human*, in 1999 – has stalled.
- Massachusetts is the only state with two distinct systems that require reporting of adverse events from some of the same facilities. While acknowledging that both systems are useful and serve different purposes, streamlining, coordinating, or potentially consolidating reporting processes across the two systems could help address provider concerns about reporting burden. Pennsylvania offers an example of how Massachusetts might consider automating and integrating data processes to enable multiple entities to respond to adverse event reports without duplicating efforts.
- A formal or informal system evaluation as was conducted by Minnesota might help Massachusetts stakeholders understand the impact of the state's reporting systems on provider or facility awareness, trust, or other patient safety issues. It could also inform strategies for improving provider experience with the two systems.
- Despite complementary goals, adverse event reporting systems in Massachusetts and elsewhere seem to stand alone from states' broad quality improvement, cost containment, and other delivery system reforms. Massachusetts has an opportunity to explicitly integrate adverse event reporting system data or patient safety more broadly into its health care system reform activities under Chapter 224 of the Acts of 2012[73] or in grant activities such as SIM.
- Regulators across the country believe that adverse event reporting systems give them valuable information, even though the systems were not designed to measure the full extent of medical harm. Most state systems are limited to information about a subset of events that cause serious patient harm, and officials acknowledge underreporting of these errors remains a problem.
- Finally, like Maryland or Pennsylvania, reporting system officials in Massachusetts could partner with other entities in the state to produce patient safety events, initiatives or learning collaboratives that leverage reporting system data to address specific areas of need.

Endnotes

1 The reporting system in Oregon is administered through the Oregon Patient Safety Commission, a semi-independent state agency charged by the Oregon Legislature with reducing the risk of serious adverse events occurring in Oregon's healthcare system and encouraging a culture of patient safety. Reports from facilities are confidential and non-discoverable. Pennsylvania's reporting system is administered through the Pennsylvania Patient Safety Authority, which was established under Act 13* of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act, as an independent state agency. The Authority's role is non-regulatory and non-punitive.

2 Massachusetts hosts two reporting systems and is therefore included twice in this count.

3 An adverse event is an injury resulting from a medical intervention (not due to the underlying medical condition of the patient) and preventable adverse events are those that are attributable to a medical error.

4 Institute of Medicine. *To Err is Human: Building a Safer Health Care System* (Washington, DC: National Academy Press, 2000), p.9.

5 Although Oregon's adverse event reporting system is voluntary, once a facility signs an agreement to participate, it commits to submitting reports.

6 To ensure that all patients are protected from injury while receiving care, NQF has developed and endorsed a set of Serious Reportable Events (SREs). This set is a compilation of serious, largely preventable, and harmful clinical events, designed to help the healthcare field assess, measure, and report performance in providing safe care.

7 Long term care centers, ambulatory clinics and home health agencies report serious incidents.

8 Applicable Massachusetts statutes and regulations are: M.G.L. c. 112, § 5, M.G.L. c. 111, § 203 and 243 CMR 3.00. (http://www.mass.gov/eohhs/docs/borim/reg-243-cmr-3.pdf)

9 There are four types of events that must be reported. The first three types of events are specific outcomes: (1) maternal death related to delivery; (2) death during or resulting from an elective ambulatory procedure; and (3) a wrong site procedure. The fourth type involves a death or "major or permanent impairment of bodily function" that was not ordinarily expected, based on the patient's condition upon presentation or admission to the facility. (243 CMR 3.08: http://www.mass.gov/eohhs/docs/borim/reg-243-cmr-3.pdf)

10 The Department of Public Health also collects reports about serious incidents (which include suicide or unanticipated death not related to the natural course of the patient/resident's death or that is the result of an error or other incident as specified by the Department's guidelines) from long term care centers, ambulatory clinics and home care providers.

11 Ambulatory surgical centers and ambulatory clinics are not required to report to California's Department of Public Health, which administers the state's adverse event reporting system, but they are required to report to the Medical Board on Adverse Events.

12 Colorado, Connecticut, Washington, DC, Florida, Georgia, Indiana, Kansas, Maine, New York, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, and Washington State

13 Oregon's reporting system is not a mandatory program, so facilities are not required to report. Hospitals, ambulatory surgical centers, long term care centers, and pharmacies submit reports. Renal dialysis facilities and freestanding birthing centers are also eligible to submit reports, but there have never been active reporting programs available for those segments.

14 2007 Guide to State Adverse Event Reporting Systems, State Health Policy Survey Report, Vol. 1, No.1 (Portland, ME: National Academy for State Health Policy, December 2007).

15 National Quality Forum (NQF), *Serious Reportable Events In Healthcare- 2011 Update: A Consensus Report.*

16 Ibid.

17 Ibid.

18 National Quality Forum (NQF), Serious Reportable Events In Healthcare—2011 Update: A Consensus Report, Washington, DC: NQF; 2011.

19 Indiana, Massachusetts Department of Public Health, Minnesota, Nevada, New Hampshire, Utah, Vermont and Washington

20 In Maryland, regulations have always required a certain state defined set of required adverse events that must be reported. However, the state uses a modified version of the NQF list for how it classifies events it receives.

21 Connecticut, Washington, DC, Illinois, Maine, New Jersey, New York, and Oregon. Respondents were given the option to select use of an NQF or state-specific list. Officials that indicated use of both a state-specific and NQF list of events or noted use of a modified or partial NQF list are categorized as a modified or partial NQF list.

22 California, Colorado, Florida, Georgia, Kansas, Maryland, BORIM, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, and Tennessee. In Pennsylvania, facilities report both harm and non-harm events, and submit any reportable event in one of 217 separate categories.

23 For more information, visit http://www.cdc.gov/nhsn/

24 2007 Guide to State Adverse Event Reporting Systems, State Health Policy Survey Report.

25 For more information, visit http://www.nashp.org/sites/default/files/use_of_adverse_data.pdf

26 Jill Rosenthal et al., Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives. (Portland, ME: National Academy for State Health Policy, 2001).

27 States collecting data electronically: Colorado, Florida, Illinois, Indiana, The Massachusetts Department of Public Health, Minnesota, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah and Vermont. States collecting data manually: Georgia, Kansas, Maryland, BORIM, Nevada, and South Dakota. States collecting data both manually and electronically: California, Connecticut, Washington, DC, Maine, New Hampshire, South Carolina, and Washington.

28 2007 Guide to State Adverse Event Reporting Systems, State Health Policy Survey Report

29 IOM, Crossing the Quality Chasm (Washington, DC: National Academy Press, 2001

30 NQF, National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report, Washington, DC: NQF; 2010

31 California, Washington, DC, Florida, Kansas, Maine, Maryland, Nevada, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, and Washington.

32 Having formally adopted NQF in 2013, Nevada has a sound basis for releasing facility-specific sentinel event statistics, as well as the authority to do so. However, the information is undergoing revision and remains unpublished.

33 Connecticut and Indiana

34 Colorado, Minnesota, and New Hampshire.

35 Georgia, Illinois, South Carolina, South Dakota, Tennessee

36 California, Connecticut, Washington, DC, Indiana, Kansas, Maine, Maryland, BORIM, Minnesota, Nevada, New Hampshire, New Jersey, Rhode Island, Utah and Vermont

37 Colorado, Florida, Massachusetts Department of Public Health, Ohio, Oregon and Washington.

38 Colorado, Connecticut, Washington, DC, Florida, Maine, Maryland, BORIM, Nevada, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Utah, Vermont and Washington.

39 California, Colorado, Washington, DC, Florida, Maine, Maryland, BORIM, The Massachusetts Department of Public Health, Minnesota, New Jersey, New York, Oregon, Pennsylvania, Tennessee.

40 Georgia, Illinois, Indiana, Kansas, Rhode Island, South Carolina and South Dakota.

41 Colorado, Washington, DC, New York, Oregon, Utah and Vermont

42 The electronic messaging system is a feature in the secure electronic NYPORTS system allowing communication between a specific facility and the New York Department of Health. This communication may involve providing feedback to a facility, seeking additional information or clarification regarding an event. Both the Department of Health and the facility have the ability to initiate communication.

43 AHRQ Patient Safety Network. Root Cause Analysis. Retrieved from http://psnet.ahrq.gov/primer.aspx?primerID=10 on September 5, 2014.

44 Centers for Medicare and Medicaid Services. Retrieved from http://cms.hhs.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicaid-and-CHIP-Compliance/PERM/Downloads/2013correctiveActionPowerpoint.pdf on September 12, 2014.

45 Connecticut, Florida, Georgia, Illinois, Indiana, Kansas, Maine, Maryland, The Massachusetts Department of Public Health, Minnesota, Nevada, New Hampshire, New Jersey, New York, Oregon, Rhode Island, South Dakota, Utah, Vermont and Washington.

46 California, Connecticut, Colorado, Florida, Illinois, Maine, Maryland, The Massachusetts Department of Public Health, Minnesota, Nevada, New Hampshire, New Jersey, Oregon, Rhode Island, South Carolina, South Dakota, Utah, Vermont, and Washington.

47 Connecticut, Florida, Illinois, Maryland, The Massachusetts Department of Public Health, Minnesota, Nevada, New Hampshire, New Jersey, Oregon, Rhode Island, South Dakota, Utah, Vermont, Washington

48 Colorado, Connecticut, Florida, Georgia, Illinois, Kansas, Maine, Maryland, The Massachusetts Department of Public Health, Minnesota, Nevada, New Jersey, New York, South Dakota and Vermont.

49 2007 Guide to State Adverse Event Reporting Systems, State Health Policy Survey Report

50 Colorado, District of Columbia, BORIM, and New York

51 Colorado, Washington, DC, Florida, Indiana, Maine, Maryland, New Jersey, Oregon, Minnesota, Nevada, Pennsylvania, South Dakota, and Vermont.

52 The Patient Safety and Quality Improvement Act signifies the Federal Government's commitment to fostering a culture of patient safety. It created Patient Safety Organizations (PSOs) to collect, aggregate, and analyze confidential information reported by health care providers.

53 Adverse Health Events 10 Year Program Evaluation, Minnesota Department of Health. January 2014. Retrieved from: http://www.health.state.mn.us/patientsafety/ae/2014ahetenyearreview.pdf on September 24, 2014.

54 California, Connecticut, Indiana, Maine, Minnesota, New Hampshire, New Jersey, New York and Utah all made specific mention of increased transparency, trust and awareness among providers and facilities.

55 Florida, Georgia, New Jersey, South Carolina, South Dakota

56 Colorado, Maryland, Oregon, Pennsylvania, Washington State

57 Patient Safety Organizations (PSOs) are required to collect and analyze data in a standardized manner. AHRQ created the Common Formats (common definitions and reporting formats) to help providers uniformly report patient safety events and to improve health care providers' efforts to eliminate harm. The Formats are broadly divided into two categories: generic ones that apply to all patient safety events and event-specific ones that relate to certain high-frequency event types. Accessed on September 30, 2014 from https://www.pso.ahrq.gov/common.

58 Hospital Engagement Networks (HENs) work at the regional, state, national or hospital system level to help identify solutions already working and disseminate them to other hospitals and providers. Retrieved from http://partnershipforpatients.cms.gov/about-the-partnership/hospital-engagement-networks/thehospitalengagementnetworks.html on September 30, 2014.

59 The Maryland Patient Safety Center is a Patient Safety Organization in Maryland that was established in 2003 by the Maryland Legislature.

60 The Maryland Hand Hygiene Collaborative is a statewide initiative to enhance the prevention of healthcare-associated infections in Maryland hospitals. The goal of the Collaborative is to achieve a better than 90 percent hand hygiene compliance rate among Maryland acute care hospitals. Being led by the Maryland Patient Safety Center, the Collaborative enjoys working relationships with the Maryland Department of Health and Mental Hygiene, Maryland Health Care Commission, Maryland Health Quality and Cost Council and the Delmarva Foundation. Retrieved from http://www.marylandpatientsafety.org/HandHyginecollaborative.aspx on September 30, 2014.

61 This collaborative supports and coordinates communications and outreach through a statewide initiative in order to assist in the reduction of both incidence and severity of patient falls in all healthcare settings in Maryland. Currently, there are 90 facilities participating-including acute care hospitals, long-term care facilities and home health agencies. The initiative has contributed greatly to preventing over 960 falls with a corresponding cost savings estimated at over $6.2 million. Retrieved from http://www.marylandpatientsafety.org/SafefromFallsinitiative.aspx on September 30, 2014.

62 In 2003, the Vermont Legislature passed Act 53, "An Act Relating to Hospital and Health Care System Accountability, Capital Spending, and Annual Budgets." One of the requirements of Act 53 is that Vermont hospitals publish annual hospital community reports containing information about quality, financial health, costs for services, and other hospital characteristics. The law also requires the Department of Banking, Insurance, Securities and Health Care Administration to publish some of that same information in a comparative format on this website. Accessed on September 30, 2014 from http://www.dfr.vermont.gov/health-care/hospitals-health-care-practitioners/hospital-report-cards

63 Jill Rosenthal and Carrie Hanlon. Nonpayment for Preventable Events and Conditions: Aligning State and Federal Policies to Drive Improvement. (Portland, ME: National Academy for State Health Policy, December 2009). Retrieved from http://www.nashp.org/sites/default/files/PatientSafety.pdf on December 11, 2014.

64 Centers for Medicare and Medicaid Services' Innovation Center. State Innovation Models: General Information. http://innovation.cms.gov/initiatives/state-innovations/

65 Alexandra Gates, Robin Rudowitz and Joceyln Guyer. An Overview of Delivery System Reform Incentive Payment Waivers. (Washington, DC: Kaiser Family Foundation, September 29, 2014). Retrieved from http://kff.org/medicaid/issue-brief/an-overview-of-delivery-system-reform-incentive-payment-waivers/ on December 11, 2014.

66 NASHP conducted stakeholder interviews in select states to produce case studies that will be published separately from this report, but provide additional information about patient safety within the context of delivery system reform.

67 A PSO is an entity listed by AHRQ that meets certain criteria established in the Patient Safety Rule. The primary activity of a PSO must be to conduct activities to improve patient safety and health care quality. Additionally, a PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care. (AHRQ Frequently Asked Questions. Accessed on October 2, 2014 from: https://www.pso.ahrq.gov/faq#WhatisaPSO)

68 Agency for Healthcare Research and Quality. Patient Safety Organizations Frequently Asked Questions Retrieved from https://www.pso.ahrq.gov/faq on September 12, 2014.

69 Several states are not making any changes to their reporting system as a result of upcoming PSO reporting relationships and requirements. They are as follows: Colorado, Florida, Georgia, Illinois, Kansas, Maine, Maryland, The Massachusetts Department of Public Health, Minnesota, New Hampshire, Nevada, New Jersey, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, and Washington.

70 Connecticut, Washington, DC, Georgia, Florida, Indiana, Maine, Maryland, BORIM, New Hampshire, New Jersey, Ohio, Rhode Island, South Carolina, South Dakota, Washington State, and Utah.

71 Kansas, Massachusetts Department of Public Health, Nevada, New York, Rhode Island, Tennessee, and Vermont.

72 California, Colorado, Illinois, Minnesota, Oregon, Pennsylvania, and Vermont.

73 Chapter 224 of the Acts of 2012 enacted a number of payment and delivery reforms in Massachusetts to facilitate health care cost containment and quality improvement. Chapter text is available at: https://malegislature.gov/Laws/SessionLaws/Acts/2012/Chapter224.