

June 2012

Update on State Government Tracking of Health Care-Acquired Conditions and a Four-State In-Depth Review

Final

Prepared for

Susannah Cafardi
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services

Mail Stop WB-06-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Prepared by

Nathan West, MPA
Terry Eng, RN, PhD (c)
Alexis Kirk, BA
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

RTI Project Number 0209853.231.002.123

Update on State Government Tracking of Health Care-Acquired Conditions and a Four-State In-Depth Review

by Nathan West, MPA
Terry Eng, RN, PhD (c)
Alexis Kirk

Federal Project Officer: Susannah Cafardi

RTI International

CMS Contract No. HHSM-500-2005-00029I

June 2012

This project was funded by the Centers for Medicare & Medicaid Services under contract no. HHSM-500-2005-0029I. The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services. RTI assumes responsibility for the accuracy and completeness of the information contained in this report.

CONTENTS

Executive Summary	1
1 Introduction.....	3
1.1 Brief Background on the Medicare Hospital-Acquired Condition Payment Policy and the Role of States in Tracking and Reporting Health Care-Acquired Conditions and Other Adverse Events	3
1.2 Changes in Approach for the Phase 3 Update on State Government Tracking of Health Care-Acquired Conditions	6
1.3 Organization of the Report.....	7
2 Methodology	9
2.1 In-Depth Review State Selection	9
2.2 Data Collection Approach.....	9
2.2.1 Document Review.....	9
2.2.2 State Reports of Health Care-Acquired Conditions.....	9
2.2.3 Telephone Interviews.....	10
2.3 Limitations	10
3 Update Findings.....	11
3.1 Update on State Medical Error and Adverse Event Reporting Systems.....	11
3.2 Update on State Use of National Healthcare Safety Network to Report Health Care-Acquired Conditions	12
3.3 State Tracking of the Medicare List of Hospital-Acquired Conditions.....	13
3.4 State Medicaid Payment Adjustment for Health Care–Acquired Conditions	17
4 In-Depth Review of Selected States	21
4.1 Four-State In-Depth Review	21
4.2 California	21
4.3 Connecticut	24
4.4 Nevada	27
4.5 Pennsylvania	30
5 Discussion and Conclusion.....	35
5.1 The Role of Recent Federal Initiatives for State Reporting and Nonpayment of Health Care–Acquired Conditions.....	35
5.1.1 <i>Hospital Compare</i> Reporting of Medicare Hospital-Acquired Conditions	35
5.1.2 Recent Federal Laws and State Expansion of the National Healthcare Safety Network for Healthcare-Associated Infections (HAIs)	35
5.2 Conclusion	37
References.....	39

Appendices

A	Medicare List of Hospital-Acquired Conditions.....	41
B	National Quality Forum List of Serious Reportable Events	43
C	In-Depth Review Discussion Topic	45

List of Figures

1.	Reporting system type by State.....	12
2.	Number of Medicare-listed hospital-acquired conditions reported by States.....	17

List of Tables

1.	Frequently used terms relating to medical errors in health care facilities	5
2.	State tracking of the Medicare list of hospital-acquired conditions	14

ACRONYMS USED IN THIS REPORT

AHRQ—Agency for Healthcare Research and Quality
BSI—bloodstream infections
CAUTI—catheter-associated urinary tract infection
CDC—Centers for Disease Control and Prevention
CDI—Clostridium difficile
CLABSI—central line–associated bloodstream infections
CLIP – central line insertion practice
CMS—Centers for Medicare & Medicaid Services
DVT—deep vein thrombosis
GAO— Government Accountability Office
HAC—hospital-acquired condition
HAC-POA—Hospital-Acquired Condition–Present on Admission
HAI—healthcare-associated infection
HCAC—health care-acquired condition
HHS—U.S. Department of Health and Human Services
HICPAC—Healthcare Infection Control Practices Advisory Committee
IOM—Institute of Medicine
MCC—major comorbidity or complication
MRSA—methicillin-resistant Staphylococcus aureus
MS-DRG—Medicare Severity-Diagnosis Related Groups
NASHP—National Academy of State Health Policy
NCD—National Coverage Determination
NHSN—National Healthcare Safety Network
NPRM—notice of proposed rulemaking
NPSD—network of patient safety databases
NQF—National Quality Forum
OHQ – Office of Healthcare Quality
OIG—Office of Inspector General
PE—pulmonary embolism
PSO—patient safety organization
RCA—root cause analysis

SIR—standardized infection ratio

SRE—serious reportable event

SSI—surgical site infection

VAP—ventilator-associated pneumonia

VRE—vancomycin-resistant enterococci

EXECUTIVE SUMMARY

Objective

To provide an update report on the status of State government tracking of health care-acquired conditions (HCACs) and conduct an in-depth assessment of four States that track a majority of Medicare Hospital-Acquired Conditions (HACs).

Background

The Deficit Reduction Act of 2005 modified payment for acute-care hospitalizations of Medicare fee-for-service beneficiaries if a complicating condition occurred during the hospitalization that could have reasonably been prevented. In response to the legislation, the Centers for Medicare & Medicaid Services (CMS) developed the Hospital-Acquired Condition (HAC) payment policy, whereby inpatient prospective payment system cases can no longer be assigned to higher-paying Medicare Severity–Diagnosis Related Groups (MS-DRGs) on the basis of reasonably preventable selected complicating conditions that are acquired during the hospital stay. CMS identified 10 categories of HACs as being preventable under accepted guideline-consistent care and targeted these for application of the HAC payment policy. CMS contracted with RTI International to evaluate the HAC payment policy. The evaluation seeks to answer a broad set of research questions, one of which is what State governments are doing to track HCACs. For each option year of the evaluation project, RTI is to submit an update report on State government tracking of HCACs. As large purchasers, regulators, and providers of health care services, States have many opportunities to improve patient safety. Reporting requirements and nonpayment adjustments for HCACs are potentially significant ways in which States can influence the cost, quality, and safety of health care.

This annual report provides an update to two previous reports: State Government Tracking of Hospital-Acquired Conditions Report prepared in June 2010 and Update on State Government Tracking of Health Care-Acquired Conditions Report prepared in June 2011. The 2010 baseline report identified and described efforts to track and report HACs and other medical errors or adverse events in all 50 States and the District of Columbia. We identified changes and additions in State governments' roles to track and report HCACs and other adverse events. In addition, we described State nonpayment policies and proposed regulations that authorize States to identify HCACs and other provider-preventable conditions for which Medicaid payment would be denied. A rule implements Section 2702 of the Patient Protection and Affordable Care Act of 2010, which directs the Secretary of Health and Human Services to issue Medicaid regulations effective as of July 1, 2011, prohibiting Federal payments to States for any amounts expended for providing medical assistance for HCACs (CMS, 2011). In addition, we conducted an in-depth assessment of four States—California, Connecticut, Nevada, and Pennsylvania—that track a majority of the Medicare HACs to learn more about their uses and validation of the data, and what quality improvement public reporting initiatives are undertaken as part of the reporting system and accompanying programs.

Key Findings

As of May 2012, 27 States and the District of Columbia enacted legislation to establish adverse event reporting systems. Twenty of these States have implemented an adverse event reporting system within the last 10 years; New Hampshire is the most recent (2010).

No Federal standards cover State reporting systems, and no uniform list of reportable events or HCACs exists. States are free to designate which events are reportable, but *harm* is a common denominator for reporting. However, beginning in July 2012, States are required to identify provider-preventable conditions that are associated with claims for Medicaid payment. Currently, 15 States use the National Quality Forum's list of 28 serious reportable events, and 12 States have identified their own sets of reportable events.

Most States with legislative mandates for reporting systems hold individual hospitals accountable for their patient care performance. Most often States performed desk audits but used on-site audits in some cases if it was determined that the hospital did not handle the event appropriately.

In 30 States and the District of Columbia, reporting of healthcare-associated infections (HAIs) is mandated. Of these States, 27 States and the District of Columbia use or will use the National Healthcare Safety Network (NHSN) as the surveillance system monitoring health care-associated events, including facility-acquired infections and reactions associated with transfusion of blood or blood products.

More than two-thirds of the States (35 and the District of Columbia) track at least one Medicare HAC. Another 15 States collect at least six Medicare HACs. States vary widely as to the total number of HACs tracked through a State-based reporting system—for example, 15 States and the District of Columbia track *all* the Medicare HACs that are part of the National Quality Forum's list of 28 serious reportable events.

Conclusion

In the absence of a nationally based mandated reporting system for medical errors and patient safety events, State-based reporting systems serve a significant role in collecting and reporting data for the Medicare HACs. Despite the wide variability in terms of what events are tracked and the reporting criteria used, State reporting systems share some common traits. They use data in similar ways to improve patient safety and employ quality improvement programs, and most of the States provide aggregated public reports. ***Current Federal initiatives have bolstered HAC reporting activities at the State level, yet overriding concerns still surround the variability and lack of standardization across State reporting systems. These differences make it unsuitable to identify national incidence and trends for HACs.***

SECTION 1 INTRODUCTION

1.1 Brief Background on the Medicare Hospital-Acquired Condition Payment Policy and the Role of States in Tracking and Reporting Health Care-Acquired Conditions and Other Adverse Events

The Deficit Reduction Act of 2005 (the Act) modified payment for acute-care hospitalizations of Medicare fee-for-service beneficiaries if a complicating condition that could have reasonably been prevented occurred during the hospitalization. Section 5001(c) of the Act requires the Secretary of the Department of Health and Human Services (HHS) to identify complications of care that meet the following three conditions: (1) are high cost, high volume, or both; (2) are assigned to a higher-paying Medicare Severity–Diagnosis Related Group (MS-DRG) when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines. In response to the Act, the Centers for Medicare & Medicaid Services (CMS) developed the Hospital-Acquired Condition–Present on Admission (HAC) payment policy, whereby inpatient prospective payment system (IPPS) cases can no longer be assigned to higher-paying MS-DRG on the basis of preventable complicating conditions that are acquired during the hospital stay.¹

To implement this payment provision, beginning in October 2007, CMS began requiring IPPS acute-care hospitals to code all *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnoses on the inpatient claim as either present on admission (POA) or acquired during the hospital stay. Through collaboration with the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and the Office of Public Health and Science (now the Office of the Assistant Secretary for Health, Office of Healthcare Quality), and after extensive public input, CMS selected 10 HAC categories that identify conditions considered to be preventable under accepted evidence-based guidelines and targeted these for application of the HAC payment policy. CMS has contracted with RTI International to evaluate the HAC payment policy. The evaluation seeks to answer a broad set of research questions, one of which is what State governments are doing to track HACs.

The Institute of Medicine’s (IOM’s) landmark publication *To Err Is Human*, released in 1999, called for a nationwide public mandatory reporting system to identify and learn from medical errors and other adverse events (IOM, 1999). Under the reporting system, State governments would be required to collect standardized information about adverse medical events that result in death and serious harm. Subsequently, the National Quality Forum (NQF) released *Serious Reportable Events in Healthcare* in 2002 (NQF, 2002). This groundbreaking document reflected consensus on a list of 28 serious, preventable adverse events that could form the basis for a national reporting system and lead to substantial improvements in patient safety. Since that time, State activity has focused on the development and improvement of reporting systems that can help improve quality and outcomes by identifying system weaknesses, complement other

¹ The IPPS is a system of payment for the operating and capital-related costs of acute-care hospital inpatient stays under Medicare Part A (hospital insurance) based on prospectively set rates.

State functions, and help safeguard the health care consumer (Rosenthal and Takach, 2007). Numerous adverse-events reporting systems are in operation, and there is growing evidence that these efforts have been bringing positive change to the quality of care delivered (Leape and Berwick, 2005).

Several States operated mandatory reporting systems before the 1999 IOM report. However, these reporting systems were used primarily to hold providers accountable for their errors and often involved public disclosure. Confidential, voluntary systems for reporting of medical errors were less common. The IOM report noted that health care providers are often reluctant to report or publicly 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 recommended the expanded use of voluntary medical error reporting systems that allow confidential reporting. Partially because of the IOM report, Congress responded with subsequent legislation to encourage and fund voluntary reporting systems and other patient safety initiatives. In 2003, CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) published guidance to States for implementation of healthcare-associated infection (HAI) public reporting, including CDC's National Healthcare Safety Network (NHSN) as a readily available resource at no cost to participants. States responded with a grassroots movement toward public reporting of HAI rates by facility with many States opting to use NHSN as the system for tracking infections.

The focus on patient safety improvement has also led State legislators to impose disclosure requirements of adverse events to patients. There is a dynamic tension between the movement for greater transparency about adverse events and the need to keep information about reported adverse events confidential to encourage reporting (Mello et al., 2005). Some State legislatures have attempted to encourage physicians and health care facilities to disclose medical errors by enacting "apology laws." Physician groups, in particular, have raised serious concerns about disclosure of medical errors. Thus, State legislators have taken steps to protect those who provide information about adverse events from suffering legal consequences. Many States have provided protections making patient safety data contained in reporting systems confidential and protected from subpoena and discovery in lawsuits (Hanscom et al., 2003). States have also passed laws to protect patient safety whistle-blowers from retaliation.

Some argue that as the public's awareness of medical errors deepens, plaintiffs' attorneys will grow more empowered and aggressive, which will in turn increase the pressure of the current tort (medical malpractice) crisis and the defensiveness of the medical profession (Mello et al., 2005). This conflict between tort liability and patient safety laws was raised at the Federal level in the early 2000s, which subsequently led to the creation of the Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act). The legislation directed HHS to create a list of public or private organizations known as patient safety organizations (PSOs), and it prohibits unauthorized disclosure of certain types of data regarding patient safety events that providers send to the PSOs (Government Accountability Office [GAO], 2010).

PSOs 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. To support PSOs and providers in their efforts to develop and adopt improvements in patient safety, AHRQ has created a network of patient safety databases (NPSDs). These

databases collect and aggregate nonidentifiable data on patient safety events voluntarily submitted by the PSOs and providers. Patient safety data are aggregated and analyzed nationally.

More recently, The American Recovery and Reinvestment Act of 2009 (the Recovery Act) authorized \$50 million to support States in the prevention and reduction of HAIs. CDC is the Federal agency responsible for distributing the Recovery Act funds to State health departments through cooperative agreements. The HAI Recovery Act supports programs to boost surveillance and prevention of HAIs, encourage collaboration, train the workforce in HAI prevention, and measure outcomes. These efforts are consistent with recommendations outlined in the *National Action Plan to Prevent Healthcare–Associated Infections: Roadmap to Elimination* (Office of Assistant Secretary for Health, 2012). NHSN will be a primary means of States’ collecting data from health care facilities through the Recovery Act agreements. NHSN is a voluntary, secure, Internet-based surveillance system operated by CDC that is open to all types of health care facilities in the United States. CDC currently supports more than 4,400 health care facilities that are using NHSN, and 27 States and the District of Columbia require or will require hospitals to report HAIs using NHSN.

Table 1 provides definitions, examples, and sources of various terms frequently referenced in documents relating to tracking and reporting of medical events that may occur in a health care facility setting. The last two terms, *health care–acquired conditions* and *provider preventable conditions*, apply more to State Medicaid nonpayment policies for conditions that extend beyond the Medicare list of HACs.

Table 1
Frequently used terms relating to medical errors in health care facilities

Term	Definition	Examples	Source
Hospital-acquired condition (HAC)	A condition that (1) is high cost or high volume or both, (2) results in the assignment of a case to an MS-DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence-based guidelines.	Foreign object retained after surgery, pressure ulcer Stages III and IV (for a complete list of HACs, see Appendix A).	Centers for Medicare & Medicaid Services: Hospital-Acquired Condition (HAC) and Present on Admission Indicator. Available from http://www.cms.gov/HospitalAcqCond/
Healthcare–associated infection (HAI)	An infection that a patient acquires while receiving treatment for one or more medical or surgical conditions.	Surgical site infection, central line–associated bloodstream infection, ventilator-associated pneumonia, and catheter-associated urinary tract infection.	U.S. Department of Health and Human Services: National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination - Executive Summary . (n.d.) Available from http://www.hhs.gov/ash/initiatives/hai/exsummary.html

(continued)

Table 1 (continued)
Frequently used terms relating to medical errors in health care facilities

Term	Definition	Examples	Source
Serious reportable event (SRE)	Unambiguous, serious, preventable adverse events that concern both the public and health care providers and could form the basis for a national reporting system that would lead to substantial improvements in patient safety. SREs are identifiable and measurable, and their risk of occurrence is significantly influenced by the policies and procedures of health care organizations.	Surgery performed on wrong patient, infant discharged to the wrong person (for a complete list of SREs, see Appendix B).	National Quality Forum: Serious Reportable Events in Healthcare 2006 Update: A Consensus Report. Available from http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare-2006_Update.aspx
Health care-acquired condition (HCAC)	A medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code that (1) is high cost or high volume, or both, (2) results in the assignment of a case to a diagnosis-related group that has a higher payment when the code is present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence-based guidelines.	Foreign object retained after surgery, pressure ulcer Stages III and IV.	Federal Register (76 FR 9283-9295). http://www.gpo.gov/fdsys/pkg/FR-2011-02-17/pdf/2011-3548.pdf
Other provider-preventable condition ¹	An umbrella term for hospital and non-hospital conditions identified by the State for nonpayment to ensure the high quality of Medicaid services. Federal minimum standard for conditions are prescribed in the Federal rule.	To be determined by States, but NPRM requires States to have reporting systems for Medicaid payment that include (at a minimum) the 10 HACs and 3 NCDs.	Federal Register (76 FR 9283-9295). http://www.gpo.gov/fdsys/pkg/FR-2011-02-17/pdf/2011-3548.pdf

¹ New term (applies more to State Medicaid nonpayment policies of conditions that extend beyond the Medicare list of HACs).

NOTE: CAUTI = catheter-associated urinary tract infection; CLABSI = central line-associated bloodstream infection; MS-DRG = Medicare Severity Diagnosis-Related Group; NCDs = National Coverage Determination; NPRM = notice of proposed rulemaking; VAP = ventilator associated pneumonia.

1.2 Changes in Approach for the Phase 3 Update on State Government Tracking of Health Care-Acquired Conditions

The purpose of this report is twofold: (1) to provide a brief update on our annual review of State government tracking of health care-acquired conditions, and (2) to conduct a more in-depth review of four selected States that track a majority of Medicare HACs and use the

collected data for statewide or regional quality improvement initiatives. In our last report, we updated our comprehensive inventory of State tracking activities of Medicare HACs conducted as part of our baseline findings, and reported an update of findings in the report *Update on State Government Tracking of Hospital-Acquired Conditions*.

1.3 Organization of the Report

In the following sections of this report, we present our methodological approach for the brief update of State-government tracking and our in-depth review of four States (**Section 2**); findings of our document review of State tracking materials to provide an update (**Section 3**); an in-depth assessment of four selected States with robust reporting systems that track a majority of Medicare HACs (**Section 4**); and a discussion of the four States' best practices or collaborations worth highlighting that make health care safer, facility performance more transparent, and ultimately improve the quality of care for their State's consumers and users of health care facilities (**Section 5**).

[This page intentionally left blank.]

SECTION 2 METHODOLOGY

2.1 In-Depth Review State Selection

We selected four States to conduct a more in-depth assessment of their reporting systems in terms of data utilization, data validity, quality improvement initiatives, and public reporting. The following criteria were used for the selection of States: (1) States that collect data on 8 to 10 categories of Medicare hospital-acquired conditions (HACs); (2) that operate a comprehensive tracking and reporting process and system for the collection of the data; (3) are representative of different U.S. Census regions (i.e., Northeast, Mid-Atlantic, and West); and (4) are representative of both small and large States in terms of population. For example, California and Pennsylvania are ranked in the top 10 most populous States, and Nevada and Connecticut are ranked in the bottom 20 (U.S. Census, 2010).

2.2 Data Collection Approach

Our data collection approach for the update report entailed the following: (1) document review of existing reports, databases, and other sources on State-level reporting initiatives for Medicare HACs and other adverse events or provider-preventable conditions; (2) collection and review of State reports that provide data on HACs and other provider-preventable conditions; and (3) semistructured interviews with State officials for the four-State in-depth review.

2.2.1 Document Review

We developed a large inventory matrix beginning in late 2009 that captures reporting system activity for the States. We are continuously updating this information as reporting activities change or go through updates. Our information derives from several sources, including recent Health and Human Services (HHS) Office of Inspector General (OIG) reports describing State adverse event reporting systems and the National Academy of State Health Policy (NASHP) patient safety toolbox (OIG, 2008; NASHP, 2010). Recent GAO reports on healthcare-associated infection (HAI) reporting systems and the role of the Patient Safety Act also informed our document review activities (GAO, 2010). Furthermore, we substantiate information collected from these research efforts by reviewing State health department or hospital association Web sites that provide information on the reporting systems or served as the site for public reporting of HAC data.

2.2.2 State Reports of Health Care-Acquired Conditions

We collected State reports, typically in the form of an annual patient safety or adverse event report, from State health department or other State government Web sites. We reviewed at least 25 State reports to determine their serious reportable event list (e.g., National Quality Forum [NQF] list or State defined), their mechanism for collecting the data, and whether the data were reported on individual facilities or in aggregate for all facilities.

2.2.3 Telephone Interviews

We conducted telephone interviews using semistructured interview guides with State officials, or their State health department designees, who direct or manage State-based reporting systems and related patient safety or quality activities. Our protocol contained discussion items that focused on uses of the data, validity of the data, degree of engagement or collaboration that the State office had in fostering patient safety or quality improvements, and the extent of publicly reported information the State captured and analyzed.

2.3 Limitations

The information in this report reflects our findings from the aforementioned document review activities and semistructured interviews with State officials. We verified that our updates on State-level information already collected from NASHP and OIG were still current and that they reflect State mandates still in place for medical error reporting. However, States' efforts to collect data and report on medical errors, particularly on HACs from the Medicare list, constitute a fluid and evolving activity in that greater Federal involvement is having an impact on HAC reporting at the State level. We cannot guarantee that all findings reflect the most recent and ongoing changes to State tracking of HACs. Furthermore, our findings assume that States are using the reported information in the manner described by their State reporting system documentation or annual State reports. We did not independently verify the validity of their description of reporting activities beyond the four States that received a more in-depth review.

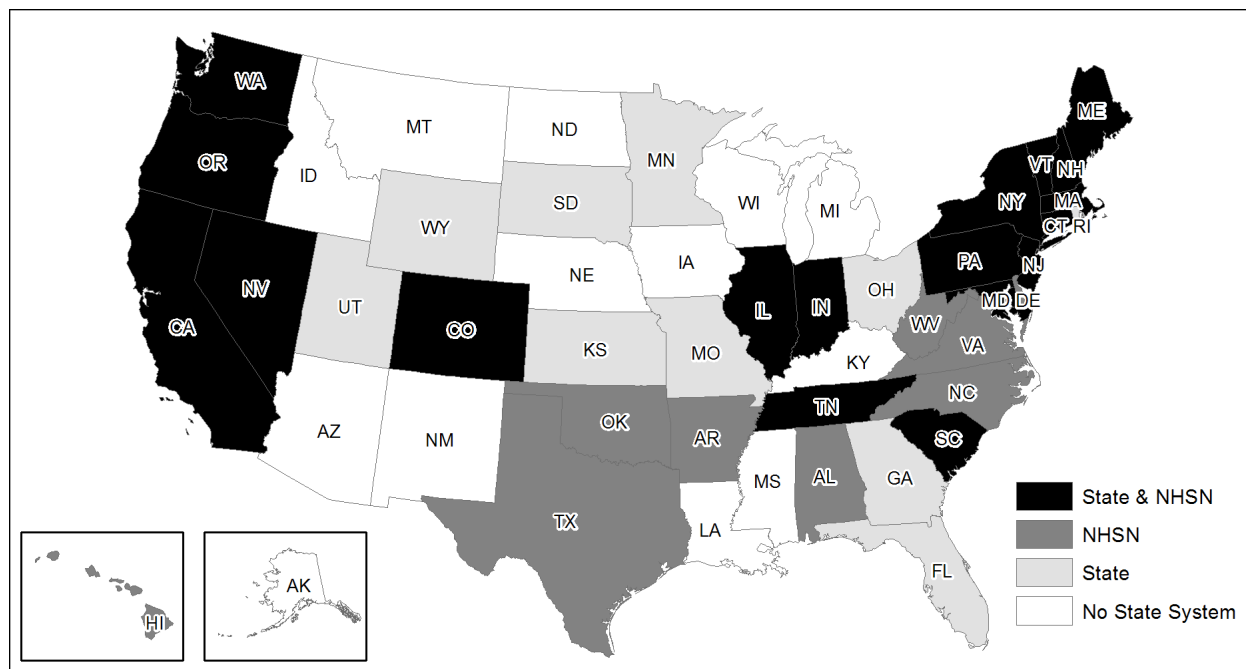
SECTION 3 UPDATE FINDINGS

3.1 Update on State Medical Error and Adverse Event Reporting Systems

The report on State Government Tracking of Medicare Hospital-Acquired Conditions published in 2010 provided a baseline report that presented findings from our initial inventory of State governments' medical error and adverse event reporting systems. Our selection of the 26 States and District of Columbia was consistent with the criteria also used by the National Academy of State Health Policy (NASHP) patient safety toolbox and the Office of Inspector General (OIG) Report on State Adverse Event Reporting Systems. In our update review of State-based reporting systems conducted in late 2011, we did not identify any new State reporting systems. In 2011, we reported that New Hampshire enacted legislation in late 2010 to require the reporting of the National Quality Forum (NQF) Serious Reportable Events (SREs) occurring in hospitals and ambulatory surgical centers. This brought the total to 27 States and the District of Columbia with an adverse event or medical error reporting system authorized by State government.

Some States authorize and operate State-based reporting systems that require facilities to report hospital-acquired conditions (HACs). States vary widely regarding which HACs are reported through these State-based reporting systems. Many States require the reporting of the NQF list of SREs, whereas others have defined their own list of events, including only a portion of the NQF events, and still others include patient safety indicators or HAIs as reportable events. Some States have both a State-based reporting system for medical errors and adverse events and track HAIs separately through NHSN. Similar to our Phase 2 findings, additional States have fallen into this category as more States go "live" with their collection of at least one HAI using NHSN. The map in *Figure 1* illustrates the different scenarios of States that operate a State-based reporting system for medical errors and adverse events, track HAIs through NHSN, or do both.

Figure 1
Reporting system type by State



NOTE: State = State-developed reporting system for medical errors/serious preventable events; NHSN = State uses National Healthcare Safety Network for reporting healthcare-associated infections (HAIs). As the map illustrates, currently 18 States (California, Colorado, Connecticut, Illinois, Indiana, Maine, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, South Carolina, Tennessee, Vermont, and Washington) and the District of Columbia both maintain a State-based reporting system for health care-acquired conditions or other adverse events and track or will soon track HAIs through NHSN. The 9 States that track HAIs through NHSN, but do not have a mandated State-based reporting system for health care-acquired conditions or adverse events are Alabama, Arkansas, Delaware, Hawaii, North Carolina, Oklahoma, Texas, Virginia, and West Virginia. Currently, 8 States (Florida, Georgia, Kansas, Minnesota, Ohio, Rhode Island, Utah, and Wyoming) maintain a State-based reporting system and do not participate in NHSN. The remaining 15 States (Alaska, Arizona, Idaho, Iowa, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Montana, Nebraska, New Mexico, North Dakota, South Dakota, and Wisconsin) neither track HAIs through NHSN nor maintain a mandated State-based reporting system.

3.2 Update on State Use of National Healthcare Safety Network to Report Health Care-Acquired Conditions

The 2009 Omnibus Bill incentivized States receiving Preventive Health and Health Services Block Grant funds (<http://www.cdc.gov/nccdphp/blockgrant/>) to submit a plan to reduce HAIs. To assist States in responding within the short time required and to facilitate coordination with national HAI prevention efforts, CDC developed a plan template. This template helped ensure progress toward national prevention targets as described in the HHS Action Plan (<http://www.hhs.gov/ophs/initiatives/hai/actionplan/index.html>), while allowing flexibility to tailor the plan to each State's specific needs. CDC also provides training support and technical assistance to States that will track HAIs using NHSN. The Department received plans for all 50 States, the District of Columbia, and Puerto Rico.

Of the 30 States and District of Columbia that have mandated reporting of HAIs, 27 States and the District of Columbia use or will use NHSN. Five States mandated NHSN use for HAI reporting during 2011: Arkansas, Hawaii, Indiana, Maine, and North Carolina. NHSN may be used to monitor health care–associated events, including facility-acquired infections, health care personnel influenza vaccination, and reactions associated with transfusion of blood or blood products. Device-associated infections are measured for bloodstream infections, urinary tract infections, and pneumonia. Surgical site infections are measured according to selected procedures. The NHSN captures central line–associated bloodstream infections (CLABSI), which is a more narrow condition than the HAC-defined vascular catheter-associated infection. Within the NHSN application, facilities can compare themselves with risk-adjusted, national aggregate data for local quality improvement purposes. Facilities can also use the system to develop surveillance and analytic methods that allow timely recognition of patient safety problems for prompt intervention. Some States without mandated or voluntary HAI reporting recently completed or have ongoing study committees considering whether to mandate HAI reporting, including Alaska, Arizona, New Mexico and Ohio. The State of New Mexico enacted the Hospital Infection Act in 2009, which formalized its HAI Advisory Committee and its role while keeping HAI data submission voluntary. The Committee is facilitated by the New Mexico Department of Health and is currently working toward its goals related to public reporting and prevention of HAIs.

3.3 State Tracking of the Medicare List of Hospital-Acquired Conditions

Table 2 shows an updated list of States that track at least one of the Medicare list of HACs. A large majority of States continue to track at least one HAC through a medical error and serious adverse event reporting system authorized and operated by a State government agency. Slightly more than two-thirds of States track at least one HAC (35 States and the District of Columbia). States vary widely among themselves as to the total number of HACs tracked through a State-based reporting system. We found that 4 States (Colorado, Illinois, Nevada, and New Jersey) track additional HACs beyond what we previously reported. Colorado added pressure ulcers, CLABSI, and deep vein thrombosis (DVT). Illinois also added CLABSI and DVT, and New Jersey legislation requires the reporting of SSIs following coronary bypass graft surgery. Nevada added the following to its list of reportable events: foreign object retained after surgery, air embolism, DVT, and blood incompatibility.

Table 2
State tracking of the Medicare list of hospital-acquired conditions

State	Foreign object retained after surgery	Air embolism	Blood incompatibility	Stage III and IV pressure ulcers	Falls and trauma	Manifestations of poor glycemic control	CAUTI	CLABSI/Vascular catheter-associated infections	Surgical site infections	Pulmonary embolism/DVT
AL	—	—	—	—	—	—	NHSN	NHSN	NHSN	—
AR	—	—	—	—	—	—	—	NHSN	—	—
CA	State	State	State	State	State	State	—	NHSN	NHSN	—
CO	—	—	State	State	State	—	—	NHSN	NHSN	State
CT	State	State	State	State	State	State	NHSN	NHSN	NHSN	—
DC	State	State	State	State	State	State	—	NHSN	—	State
DE	—	—	—	—	—	—	—	NHSN	—	—
FL	State	—	—	—	—	—	State	State	State	State
GA	—	—	—	—	State	—	—	—	—	—
HI	—	—	—	—	—	—	—	NHSN	NHSN	—
IL	State	State	State	—	State	State	—	NHSN	NHSN	State
IN	State	State	State	State	State	State	NHSN	NHSN	NHSN	—
ME	State	—	State	State	State	—	—	NHSN	—	—
MD	State	State	State	State	State	State	—	NHSN	—	—
MA	State	State	State	State	State	State	—	NHSN	NHSN	—
MN	State	State	State	State	State	State	—	—	—	—
MO	—	—	—	—	—	—	—	State	State	—
NV	State	State	State	State	State	State	State	NHSN	NHSN	State
NH	State	State	State	State	State	State	—	NHSN	NHSN	—
NJ	State	State	State	State	State	State	NHSN	NHSN	NHSN	—
NY	State	—	—	—	State	—	—	NHSN	NHSN	State
NC	—	—	—	—	—	—	NHSN	NHSN	NHSN	—
OK	—	—	—	—	—	—	—	NHSN	—	—
OH	State	—	—	State	—	—	—	State	State	—
OR	State	State	State	State	State	State	—	NHSN	NHSN	—

(continued)

Table 2 (continued)
State tracking of the Medicare list of hospital-acquired conditions

State	Foreign object retained after surgery	Air embolism	Blood incompatibility	Stage III and IV pressure ulcers	Falls and trauma	Manifestations of poor glycemic control	CAUTI	CLABSI/Vascular catheter-associated infections	Surgical site infections	Pulmonary embolism/DVT
PA	State	State	State	State	State	State	NHSN	NHSN	NHSN	State
RI	—	—	—	—	State	—	—	—	—	—
SC	—	—	State	—	State	—	—	NHSN	NHSN	—
TN	State	—	State	—	State	—	—	NHSN	NHSN	—
TX	—	—	—	—	—	—	—	NHSN	NHSN	—
UT	State	State	State	State	State	State	—	—	—	—
VT	State	State	State	State	State	State	—	NHSN	NHSN	—
VA	—	—	—	—	—	—	—	NHSN	—	—
WA	State	State	State	State	State	State	—	NHSN	NHSN	—
WV	—	—	—	—	—	—	—	NHSN	—	—
WY	State	State	State	State	State	State	—	—	—	—

NOTE: A dash (—) signifies that the State does not track the condition; CAUTI = catheter-associated urinary tract infection; CLABSI = central line-associated bloodstream infection; DVT = deep vein thrombosis; NHSN = State uses or will use the National Healthcare Safety Network for mandatory health care-associated infection reporting; State = State-developed reporting system for medical errors or adverse events.

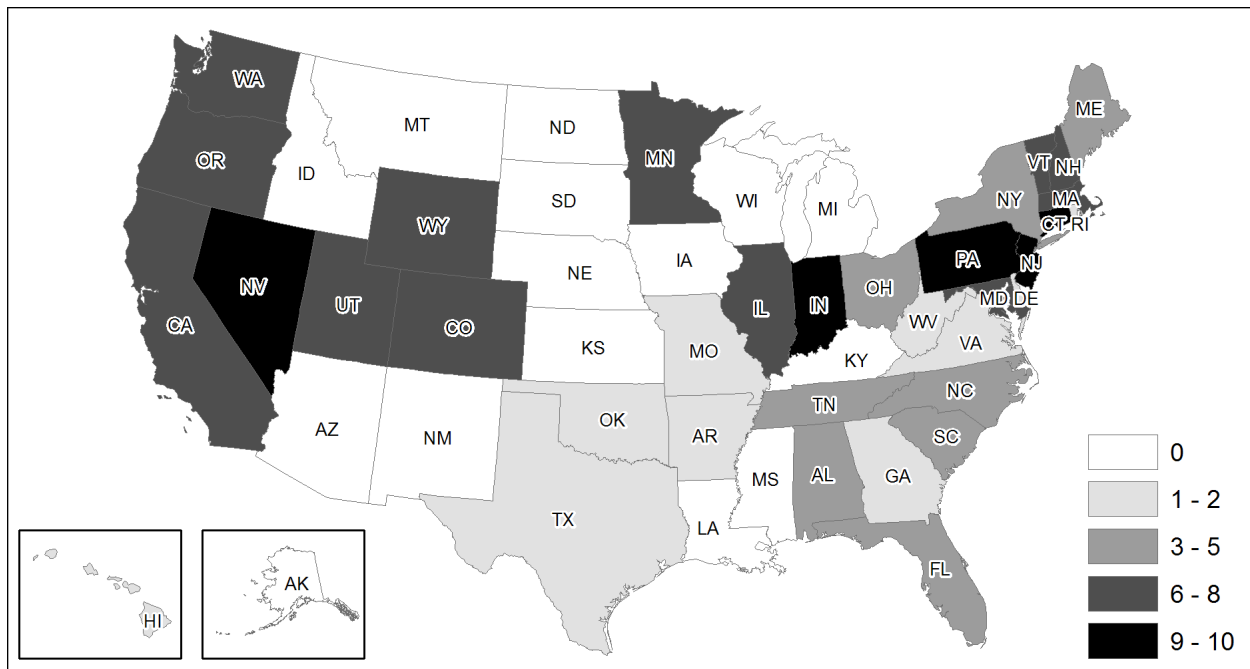
As previously noted, New Hampshire recently enacted legislation requiring the reporting of the 28 NQF serious reportable events. This results in 15 States and the District of Columbia that track all HACs that are part of the NQF's list of 28 SREs. These HACs are (1) foreign object retained after surgery, (2) air embolism, (3) blood incompatibility, (4) Stage III and IV pressure ulcers, (5) falls and trauma, and (6) manifestations of poor glycemic control. These States use the NQF list of SREs or a modified version of that list as the HACs that facilities are required to report.

Outside of these six HAC categories that are also on the NQF list, three of the HAC categories from the Medicare list are HAIs that many States track through various initiatives. Three States (Nevada, New York, and Pennsylvania) historically tracked selected HAIs through their State's adverse event report systems, but these States recently underwent a transition period to now track HAIs through the NHSN. Connecticut continues to track nosocomial or healthcare-associated infections that result in death or serious injury through its adverse event reporting system, and also mandates reporting CAUTI, CLABSI, and SSI through the NHSN. A subset of vascular catheter-associated infections, CLABSI continues to be the HAI most commonly required to be reported through NHSN: 27 States and the District of Columbia either require or will require reporting of the infection type. Peripheral line infections, another subset of vascular catheter-associated infections, are not reportable to NHSN. Reporting of surgical site infections via NHSN is or will be mandated by 20 States, whereas only 6 States require reporting of CAUTI via NHSN. Many more States plan to begin using NHSN to track at least one HAI as part of their HAI Recovery Act State Plan. CDC reviewed these plans to help understand how State activities can contribute to the HHS HAI goals, identify gaps, and determine means of additional support. The Office of Healthcare Quality (OHQ) has since offered project funding to address some of these gaps.

States not listed do not track any of the Medicare HACs through a State-authorized reporting system or NHSN. It is possible that some reports are submitted through PSOs for certain States and are not listed here. Such reports would not necessarily, or likely, be reported statewide, given that individual health care facilities have agreements with a State-designated PSO to voluntarily and confidentially report medical errors.

As **Figure 2** shows, five States (Connecticut, Indiana, New Jersey, Nevada, and Pennsylvania) collect 9 to 10 categories of Medicare HACs. Twelve States plus the District of Columbia collect 6 to 8 HACs: California, Colorado, Illinois, Maryland, Massachusetts, Minnesota, New Hampshire, Oregon, Utah, Vermont, Washington, and Wyoming. Another eight States (Alabama, Florida, Maine, New York, North Carolina, Ohio, South Carolina and Tennessee) collect between 3 and 5 HACs. Ten States (Arkansas, Delaware, Georgia, Hawaii, Missouri, Oklahoma, Rhode Island, Texas, Virginia, and West Virginia) collect either 1 or 2 HACs.

Figure 2
Number of Medicare-listed hospital-acquired conditions reported by States



3.4 State Medicaid Payment Adjustment for Health Care–Acquired Conditions

CMS issued a notice of proposed rulemaking (NPRM) on February 17, 2011, that provides guidance for States to implement Section 2702 of the Patient Protection and Affordable Care Act of 2010 (CMS, 2011). This Section directs the Secretary to issue Medicaid regulations effective as of July 1, 2011, prohibiting Federal payments to States under Section 1903 of the Social Security Act for any amounts expended for providing medical assistance for health care–acquired conditions (HCACs) and other provider-preventable conditions (PPC). It also authorizes States to identify other provider-preventable conditions for which Medicaid payment would be prohibited. Such regulations must ensure that the prohibition of payment for HCACs does not result in a loss of access to care or services for Medicaid beneficiaries.

In a preamble to the final rule, CMS stated that compliance action would not be undertaken against States under the PPC rule until July 1, 2012. CMS did so noting that States may need additional time to develop and complete the implementation of sound PPC policies. This delay in CMS compliance action is not the same as authorizing States to delay submitting conforming State Plan Amendments (SPAs). CMS expects that States will submit such amendments to CMS but recognize that States may face unavoidable delays as the new policies are communicated to providers and implemented through the State’s claims processing systems. At the time of this writing (March 2012), CMS had approved 6 revised SPAs and had received 35 more, which were under review for CMS approval.

The minimum set of conditions, including infections and events, that States must identify for nonpayment are as follows:

Category 1 – Healthcare-Acquired Conditions (HACs) (for Any Inpatient Hospital Settings in Medicaid)

- Foreign Object Retained After Surgery
- Air Embolism
- Blood Incompatibility
- Stage III and IV Pressure Ulcers
- Falls and Trauma; including Fractures, Dislocations, Intracranial Injuries, Crushing Injuries, Burns, Other Injuries
- Catheter-Associated Urinary Tract Infection (CAUTI)
- Vascular Catheter-Associated Infection
- Manifestations of Poor Glycemic Control; including Diabetic Ketoacidosis, Nonketotic Hyperosmolar Coma, Hypoglycemic Coma, Secondary Diabetes with Ketoacidosis, Secondary Diabetes with Hyperosmolarity
- Surgical Site Infection Following
 - Coronary Artery Bypass Graft (CABG) - Mediastinitis
 - Bariatric Surgery; including Laparoscopic Gastric Bypass, Gastroenterostomy, Laparoscopic Gastric Restrictive Surgery
 - Orthopedic Procedures; including Spine, Neck, Shoulder, Elbow
- Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) Following Total Knee Replacement or Hip Replacement with pediatric and obstetric exceptions

Category 2 – Other Provider Preventable Conditions (for Any Health Care Setting)

- Wrong surgical or other invasive procedure performed on a patient
- Surgical or other invasive procedure performed on the wrong body part
- Surgical or other invasive procedure performed on the wrong patient
- OPPCs identified in the State's plan and according to the requirements of the final regulation

Under Medicaid, States must deny payments in any inpatient hospital setting for the identified PPCs. This includes Medicare's IPPS hospitals, as well as other inpatient hospital settings that may be IPPS exempt under Medicare, or that States identify as inpatient hospital settings in their Medicaid plans. This also includes Critical Access Hospitals that operate as inpatient hospitals. States can expand beyond minimum requirements for identifying PPCs. The regulation defines two separate categories of PPC, Health Care–Acquired Conditions (HCACs) and Other Provider Preventable Conditions (OPPCs). The conditions identified for the HCAC category are defined as Medicare's Hospital Acquired Conditions (HACs) and can only be changed as a result of a change to Medicare's HACs. States have no authority under these provisions to identify additional HCACs other than to update their Medicaid plans to reflect changes in Medicare HACs. OPPCs that occur in any health care setting in accordance with the regulations must be as follows:

- identified in the State plan;
- have been found by the State, based upon a review of medical literature by qualified professionals, to be reasonably preventable through the application of procedures supported by evidence-based guidelines;
- of negative consequence for the beneficiary; and
- auditable.

The Center for Medicaid and State Operations (CMSO) issued a survey to States in 2011 to obtain information on current State Medicaid practices for prohibiting payments for HCACs. CMS found that 21 States have HCAC-related nonpayment policies, most of which identify at least the Medicare HACs for nonpayment in hospitals. Half exceeded the Medicare policies in terms of the conditions, systems used to indicate the conditions, or the settings to which the nonpayment policies apply. A detailed summary of CMSO's findings was provided in last year's Report on State Tracking of HCACs.

[This page intentionally left blank.]

SECTION 4 IN-DEPTH REVIEW OF SELECTED STATES

4.1 Four-State In-Depth Review

For the in-depth assessment of the four selected States, our key findings reflect the following domains: data utilization, data validity, quality improvement, and public reporting. Data utilization refers to how the State collects data on Medicare hospital-acquired conditions (HACs), including healthcare-associated infections (HAIs), and how it uses that information. Data validity refers to whether the State has a mechanism for auditing the collected data for accuracy and validity. Data validity also includes information on how States provide a more clinical review of submitted incident reports or HAC data, and what processes are used to clarify or correct submitted data. In assessing the quality improvement domain, RTI queried the four States about clinical improvement outcomes, the impact of the HAC payment policy on addressing quality issues, and whether and how adverse event-level data are shared with providers for quality improvement purposes. The public reporting domain refers to the level of information and how the data are reported publicly. RTI queried the four States to determine whether there has been any response from the public regarding the information and/or validity of the data.

We also asked interview participants their opinion of the feasibility of creating and using a national database for collecting HACs. As noted in the Methodology section, each domain was assessed using a variety of resources: State health department Web sites specific to adverse event reporting, State annual reports providing aggregate or facility-specific HAC or other adverse event rates, and interviews with key State informants (Appendix C).

4.2 California

California has two reporting systems for tracking HACs and other adverse events: (1) an adverse event reporting system that is part of the California Department of Public Health (CDPH), and (2) the use of the National Healthcare Safety Network (NHSN) for the tracking of HAIs. California initiated its adverse event reporting system in 2007, responding to State legislation that mandated the reporting of a modified list of the National Quality Forum (NQF) Serious Reportable Events. The reportable events are grouped into the six NQF categories: surgical, product or device, patient protection, care management, environmental, and criminal. General acute-care hospitals, acute psychiatric hospitals, and special hospitals are required to report an adverse event to the CDPH no later than 5 days after the adverse event has been detected, or, if the event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, no later than 24 hours after the adverse event has been detected. All of the Medicare HACs are tracked by one of these two reporting systems with the exception of catheter-associated urinary tract infection (CAUTI) and Deep Vein Thrombosis/Pulmonary Embolism.

California's HAI program, which was authorized in 2009, evolved from three legislative mandates: SB 739 (2006), SB 1058 (2008), and SB 158 (2008). SB 1058 mandates the reporting of central line-associated bloodstream infections (CLABSI) and surgical site infections (SSIs) following orthopedic, cardiac, and gastrointestinal surgery; both are part of the Medicare

HAC list. The mandate also included two of the previously considered HACs, Clostridium difficile infections (CDI) and methicillin-resistant staphylococcus aureus (MRSA), and two additional infections: vancomycin-resistant enterococci (VRE) and bloodstream infections (BSI). Quarterly reporting of these infections is now conducted through the NSHN, as of January 2011.

The goal of both the State and NHSN reporting systems is to promote safety by providing public disclosure of medical errors to the public, consumers, purchasers of health care, and providers with reliable information about acute-care hospitals in California. Data are reported in the aggregate and by facility and are used for regulatory purposes as well. In 2011, California initiated a retroactive quality assessment process to identify quality outliers and follows up with facilities to identify opportunities for future improvements in surveillance, reporting, prevention, and control.

Data Utilization: The CDPH Licensing and Certification office publishes an annual report on adverse events according to the above NQF categories. The data are obtained from the Federal Automated Survey Processing Environment (ASPEN) database. ASPEN is a dynamic database, which is updated constantly, and tracks reported adverse events and complaints reported by health care facilities. The state aggregated data are presented in several ways: (1) by NQF adverse event category and type, (2) by volume and percentage of adverse events category, annual count of adverse events that involve an ongoing threat of imminent danger by event category, and (4) failure to report adverse events statistics by State fiscal year with the annual amount of penalties assessed for nonreporting.

In February 2012, the CDPH's Center for Health Care Quality announced an opportunity for hospitals to participate voluntarily in the development of a new, secure Web portal: The California Healthcare Event and Reporting Tool (CalHEART). Health facilities and providers will be able to self-report adverse events to CDPH and access HAI data for their facility. The implementation of CalHEART is intended to allow CDPH to improve data analysis processes, conduct investigations, report results, and facilitate performance improvement by providing trend and historical information on health care providers. It is anticipated that this new database will allow patients and consumers to make informed decisions about selecting a health care facility (CHA, 2012).

CDPH may assess a civil penalty for an adverse event that is not reported and an administrative penalty for an adverse event that poses immediate jeopardy to the health and safety of a patient. Immediate jeopardy is defined as a situation in which the hospital's noncompliance with a condition of licensure is likely to cause serious injury or death to the patient. Retention of a foreign object in a patient after surgery or other procedure (California SB 1301, Health and Safety Code, Section 1279.1(b) (1-D)) is an example of a HAC that would incur an administrative penalty. The penalty for failure to report an adverse event is \$100 for each day not reported. The administrative penalty is a civil monetary penalty in an amount of up to \$100,000 per violation or deficiency. The money collected from these penalties is placed in a State-funded account for quality improvement and is used for medical safety issues.

In 2010, two HAI-associated reports were publicly reported: Healthcare-Associated Bloodstream infections in California Hospitals and Healthcare-Associated Clostridium difficile infections in California Hospitals covering the period of January 2009 through March 2010. In

January 2012, the second year of the program, CLABSI, MRSA, VRE Bloodstream Infections, CDI, Central Line Insertion Practice (CLIP) Adherence in Intensive Care Units, and SSIs were reported.

Data Validity: As part of California's HAI program, HAI liaison teams, composed of experienced infection preventionists, are regionally located throughout the State to provide consultation to hospitals on prevention, surveillance, and reporting. Liaison infection preventionists identify best practices, seek to understand HAI priorities and needs of hospitals, providing direct assistance, and making recommendations of HAI prevention resources, tools, and prevention collaboratives. As of June 2011, the Liaison Program began offering data validation to the first 100 volunteer hospitals. These 100 hospitals provide information back to the HAI program. The intent is to learn and strategize how the data can be used to improve care.

Quality Improvement: California is mandated to publicly disclose information on hospital-specific rates for CLABSI, MRSA, VRE, CDI, and SSIs. In January 2012, California published six reports on these data, including CLIP, which was the first project to submit data of its kind into CDC's NHSN. Since 2009, all general acute-care hospitals in California are required by statute to report quarterly to the CDPH SSIs involving orthopedic, colon, and coronary artery bypass graft (CABG) surgeries. As of January 2012, California general acute-care hospitals are required to post individual hospital rates of SSIs for these surgeries on the CDPH Web site. To this end, the CDPH has developed and posted on its Web site, an Interactive Map of Surgical Site Infections for colon surgery, CABG, hip replacement, and knee replacement surgeries for each reporting hospital. The data are specific to individual hospitals and provide information on the number of surgeries performed by type, the number of SSIs, and whether the infection rate is within the standardized infection ratio¹ (SIR). For example, Cedars-Sinai Medical Center performed 224 hip replacement surgeries between April and June 2011. There were 2 infections during this time period and the SIR was within the predicted range.

The CDPH has previously published reports on both CLIP and CLABSI. The most current report (January 2012) using data reported from April 1, 2010, through March 31, 2011, is the second on CLABSIs developed by CDPH, and the first report using data submitted by hospitals using NHSN. The CDPH views the CLIP data as an opportunity for quality improvement and recommends that hospitals link the CLIP adherence monitoring data with CLABSI surveillance data to link prevention practices with infection outcomes. California is currently working on collecting data on CAUTI.

MRSA and VRE incidence rates are reported by individual hospital and by category of hospital: acute care, long-term care, and so on. Prior to the current report, a comparison among hospitals and types of hospitals was not available given that there was no standard definition of bloodstream infection. There are no other reports of MRSA or VRE incidence rates from NHSN rates for comparison with this report, so it is not possible to compare these California hospital-

¹ A SIR is a summary statistic used to measure relative difference in HAI occurrence during a reporting period compared with a common referent period (e.g., standard population). In HAI data analysis, the SIR compares the actual number of HAIs with the predicted number based on the baseline U.S. experience (e.g., standard population), adjusting for several risk factors that have been found to be most associated with differences in infection rates. More information is available at: <http://www.cdc.gov/hai/national-sir-jan-dec-2010/background.html>

specific rates with U.S. rates or rates reported by other States. As more States begin to report bloodstream infections (BSIs) through NHSN, it will be possible to make comparisons across hospitals, types of hospitals, and across States because CDC has developed a standard definition for BSIs. The CDPH views this report as an opportunity to continue to work with its hospitals to improve data-reporting accuracy and validity by sending reports from NHSN to facilities so that data errors can be addressed.

The most recent report on CDI (January 2012), a previously considered HAC, using data reported from April 1, 2010, through March 31, 2011, is the second report published by the CDPH and the first report using NHSN data. California is the second state—New York was the first—to publish these data through NHSN. Similar to the recommendations from the January 2012 MRSA/VRE report, California views this report as an opportunity to improve data quality for future comparisons using currently available CDC standardized definitions for CDI.

Public Reporting: California has a robust public reporting system on the CDPH Web site. California Health and Safety Code Section 1288.55 (c) (1) requires the CDPH to publicly disclose information on hospital-specific rates of CLABSI, MRSA, VRE, CDI, and SSIs. All of the recently published reports on HAI data are posted on the Web site and are accessible to the public. Data are presented in aggregate statewide, by individual California facility, and for CLABSI specific incidence details are reported: central line days and patient days, CLABSI rates and their 95% confidence intervals, device (central line) utilization ratios, and symbols indicating patient care locations that were significantly higher or lower, or no different from statewide average rates (CDPH, 2012). CDPH supports the goals of public reporting by encouraging the public to use the information contained in these reports to discuss patient safety issues with their health care providers and their specific hospital staff so they are informed about measures that their hospital is taking to ensure their safety. Although there has been little response to the reports from the public to date, the California Consumers Union has been positive in its publications regarding the public release of this information.

When asked about the feasibility of creating a national database for collecting adverse medical events specific to the HACs, California contended that CMS could use current claims data for these purposes. California also indicated that to develop a national database, standard definitions and measurements would have to be developed in order to make comparisons across hospitals, States, and at the national aggregate level. Databases of this nature are seen as a mechanism for State agencies to benchmark with health care and insurance providers as well as to compare hospital-level rates with national rates or rates reported by other States.

4.3 Connecticut

Connecticut has two reporting systems for tracking HACs and other adverse events: (1) an adverse event reporting system that is part of the State Department of Health's (DPH's) Quality in Health Care Program, and (2) HAI reporting through the NSHN, which is overseen by a HAI Committee that is separate from the Quality in Health Care Program. The Connecticut adverse event reporting system is, by design, focused on serious, preventable events with the intent of both regulatory accountability and quality improvement.

Event Types: State-mandated adverse event reporting began in 2002. This original reporting system was not related to the NQF Serious Reportable Events list, but after 2 years of program evaluation the decision was made to adopt the NQF's list along with five to six State-specific events. The revised list of reportable events went into effect in 2004; mandated regulations for reporting became effective in November 2007. The revised list includes all NQF serious reportable events plus seven state-specific events:

- Perforations during open, laparoscopic, and/or endoscopic procedures resulting in death/serious injury.
- Patient death or serious injury associated with a fall while being cared for in a health care facility.
- Obstetrical events resulting in death or serious disability to the neonate.
- Significant medication reactions resulting in death or serious disability.
- Laboratory or radiologic test results not reported to the treating practitioner or reported incorrectly that result in death or serious disability due to incorrect or missed diagnosis in emergency department.
- Nosocomial infections resulting in death or serious injury.
- Patient death or serious disability as a result of surgery.

As opposed to the original State-based list of reportable events, adoption of the NQF list has allowed for greater comparability between States. Reporting year 2011 was the first year that facility-level rates were publicly reported. Subsequent to the structural change in adverse event reporting, the Connecticut State legislature also provided funding for HAI reporting in 2006. As of 2012, required reporting of HAIs includes CLABSI, CAUTI, and SSIs associated with colon and hysterectomy procedures. Between the two reporting programs, Connecticut receives data for all 10 Medicare HACs.

Data Utilization: Adverse event reporting is required by acute-care hospitals, chronic care hospitals and hospices, hospitals for the mentally ill, ambulatory surgical centers, pain medicine centers, fertility centers, and outpatient childbirth centers. All reports are sent to the DPH either by telephone or fax. Currently, Connecticut does not have any intentions of switching to an electronic reporting system. Once a report is received at the DPH, data are entered into a database. The DPH shares these data with the public through two primary mechanisms: an annual report and through briefings from biannual subcommittee meetings open to the public. In late 2011, the DPH electronic database contained 1,637 reports.

HAIs are reported through CDC's NHSN. Mandated facility types in Connecticut closely follow the CMS IPPS list of acute-care hospitals—with a slight variation in that Connecticut also includes children's hospitals. In 2012, all hospitals licensed by DPH as a general or children's hospital are required to report CLABSI from all adult and pediatric ICUs, and all level II/III or

III neonatal ICUs. They are also required to report CAUTI from all adult and pediatric ICUs; and abdominal hysterectomy and colon surgery procedure–associated surgical site infections.

Data Validity: The State does not have a systematic way to validate data as part of its adverse event reporting system. The DPH does, however, have a system in place to investigate reported incidents, which includes a thorough clinical review of each report. The first line of investigation lies with the reporting facility: under Connecticut State law, facilities are required to submit a corrective action plan to the DPH for each adverse event. External investigations may be initiated via the following:

- direct complaint by any person to DPH;
- following a sentinel event report by the facility to the Joint Commission, a complaint to the Joint Commission by any person, or unannounced onsite visit to facility by the Joint Commission during which an adverse event occurs; or
- screening of adverse event report by DPH. DPH will investigate whether an adverse event was due to inadequate standards of care. These investigations determine regulatory compliance and provide information that may allow one to determine whether the event was in fact caused by inadequate care or simply a medical error/systems issue. In addition to this inspection, review of clinical records, interviews with staff and vested parties may also be conducted, when appropriate.

A large concern with this reporting system, as with all adverse event reporting systems, is under-reporting. To help safeguard against under-reporting, in 2010 the Connecticut DPH expanded screening of death records for possible under-reported, fatal adverse events. Thus far, no unreported events have been found through this method.

Patient Safety and Quality Improvement Initiatives: Connecticut has three patient safety organizations (PSOs) that are primarily responsible for the State’s quality improvement initiatives. The DPH’s three designated PSOs are the Qualidigm PSO—composed of a diverse group of providers from acute-care and long-term care hospitals, specialty and behavioral health facilities; the Connecticut Hospital Association PSO, which is also a federally designated PSO; and the Ambulatory Surgical Center PSO. The PSOs are completely separate from the regulatory body, and the DPH primarily cooperates with the PSOs to promote the adoption and development of best practices. Independence of the PSOs and the confidentiality of their data are protected under the 2005 Patient Safety Act. The health care provider can submit reports, records, analyses, policies, procedures, or root cause analyses directly to the PSO. The PSO will then disseminate appropriate information or recommendations on best medical practices and systems changes to improve patient care. Recipients of such information include not only the health care providers themselves but also the DPH, the Quality of Health Care Advisory Committee, and the general public.

Main activities within each of the PSOs include the following:

- **Qualidigm PSO**—In 2010–2011, Qualidigm offered four full-day and one half-day educational programs. Each program had a specific patient safety agenda and targeted practical strategies that could be implemented at each facility.
- **Connecticut Hospital Association (CHA) PSO**—All but two of Connecticut’s nonprofit hospitals participate in this PSO. Since 2007 the CHA has launched four statewide clinical collaboratives for topics including Pressure Ulcer Prevention, Multiple Drug-Resistant Organisms, Patient Falls with Injury, and Reducing Heart Failure Readmission. The CHA also has Learning Communities, and hospitals in this PSO are participating for the third year in a national CLABSI prevention project. In fall 2011, the CHA expanded this effort to also include CAUTI. Other initiatives from this PSO include the Patient Safety Summit, an annual education summit for health care leaders; the Quality Institute, which offers a series of education curricula and tools; and patient resources, including the CHA Quality reporting Web site.
- **Ambulatory Surgical Center (ASC) PSO**—It strives to create an environment of compliance for infection control. Main focuses in the past year included an ongoing Hand Hygiene compliance study and a safe injection initiative. Sixty ASCs are current, active participants in this PSO.

At the facility level, most facilities look for trends within their adverse event/HAI data and create Quality Improvement initiatives around any such emergent trends.

Public Reporting: The DPH’s primary vehicle for public reporting of adverse event and HAI data is through its annual reports available on its Web site. In an effort to increase transparency in health care, the State legislature mandated that adverse event data be reported on a facility level beginning in 2011. Both the adverse event and HAI reporting programs author annual reports and both provide facility-level data.

Data for Medicare HACs, however, are also available on the CHA Web site. The association’s Hospital Quality Reporting Web site, <http://www.chime.org>, also offers facility-level data specific to Medicare HACs. These HAC data are from CMS Medicare administrative data that Connecticut hospitals report on a quarterly basis at the Federal level. Data displayed on the CHA site are similar to the way data are presented on CMS’ Hospital Compare site (<http://www.hospitalcompare.hhs.gov>), in that facility-level rates are shown in comparison with national averages. Although the data provided on the CHA site are easy to access and presented in a way that is patient friendly, again, data provided here are not associated with any State-level reporting initiatives.

4.4 Nevada

Nevada has a comprehensive sentinel event registry that was mandated by statute in 2002 and requires the reporting of sentinel events. In 2005 the Nevada legislature codified “facility acquired infection” as a reportable sentinel event. The State law defines a sentinel event as “an unexpected occurrence involving facility-acquired infection, death or serious physical or

psychological injury or the risk thereof, including, without limitation any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. The term includes a loss of limb or function.” (Accessed 2-16-12 from http://health.nv.gov/Sentinel_Events_Registry.htm.) Hospitals, obstetric centers, surgical centers for ambulatory patients, and independent centers for emergency medical care are mandated by statute to report sentinel events to the Nevada Sentinel Event Registry, which is completed by the Office of Public Health Informatics and Epidemiology and maintained by the Nevada State Health Division (NSHD).

Sentinel events are categorized by the type of event that occurred and follow the NQF categories: surgical, product or device, patient protection, care management, environmental, and criminal. In addition, Nevada has added two other categories: HAI, which includes the subcategories of CLABSI, Ventilator-associated pneumonia (VAP), SSIs, and CAUTI. The “other” category includes other HAIs and other events not included in the other categories. In the future, Nevada plans to collect data on events according to national standards.

Data Utilization: Sentinel events are reported to the NSHD through the use of an electronic form that is sent by certified mail on a periodic basis to generate annual reports. Prior to 2011, there were prohibitions on reporting data by facility-specific sentinel event rates, but recent legislation now allows for this. Nevada is currently working through the methodology for reporting any facility-level data and therefore has not released facility-specific reports. Reporting of sentinel events as defined by Nevada has a level of subjectivity that makes comparisons between facilities problematic, but future plans to collect data according to national standards should lessen this subjectivity. Currently, Nevada generates statistics on patient surgery incidents such as foreign object retained after surgery, using CMS billing data and not its sentinel event registry. Nevada continues to collect data on all 10 HACs using CMS billing data, which are also used to support auditing of sentinel events.

More HACs are identified from the billing system than from the sentinel event registry. Hospitals have been asked to report HACs through the sentinel event registry when a HAC has been identified through the CMS claims system. There is some redundancy between this system and the sentinel event registry. At this time, Nevada is limited by what it can report and which vehicle it can use to report it.

The major reason for collecting the sentinel event data is to meet legal requirements and to disseminate information to the public. Information from the sentinel event registry is incorporated into a process where this information along with that from other data sources is compiled for facility-specific data. Facility surveyors use the compiled sentinel event data to help steer, direct, or inform activities while doing routine surveys of facilities. Facilities receive feedback from surveyors and inspectors and conduct educational sessions on sentinel events. Identified deficiencies from the surveys and suggested improvement actions are contained in the survey reports.

Data Validity: The Sentinel Event Registry is audited regularly for validity and accuracy. For example, if a health facility surveyor comes across a sentinel event during the course of his or her inspection, the surveyor completes a form that is electronically submitted to the sentinel event registry. This information is used to cross-reference with the sentinel event

registry. If there is a discrepancy, follow up is conducted with the facility to determine whether the event qualified as a sentinel event.

Quality Improvement: Infection prevention and control data are used for quality improvement purposes. Since March 2009, the NSHD Bureau of Health Care Quality and Compliance (BHCQC) employs an infection preventionist and associated Education Prevention Intervention (EPI) Team for the purpose of providing education and consultation in infection prevention and control for all Nevada health care facility types regulated by BHCQC. In addition, the EPI team provides support, education, and consultation to the BHCQC surveyors. The EPI Team works out of the Office of Epidemiology and acts as a consultant to facilities regarding their infection control prevention and control practices. This team is in contrast to the hospital survey team and is nonpunitive. The EPI team is contacted by a specific facility that has had a sentinel event for assistance with instituting systems changes in order to make process improvements. Because the sentinel event data have been protected in the last 2 years, facilities feel comfortable contacting the EPI team for assistance. Some of the programs that have been implemented through this consultation are hand hygiene, prevention of multi-drug resistant (MDR) organisms, equipment and environmental cleaning, and infection control risk assessment planning.

As an outcome of these efforts, rural hospitals in Nevada, which traditionally do not have infection control programs, have formed their own infection control collaborative. They meet every 2 months and focus on some process measure that is being addressed on a national level. They have formed a CLABSI, CDI, and CAUTI collaborative. Data from the NHSN and the sentinel event registry are used for quality improvement around infection control and prevention. Hospitals work with the EPI team to identify processes to improve infection practices and outcomes. An opportunity for quality improvement identified through State regulatory surveys of hospitals is also used to conduct quality improvement processes.

Adverse event data are shared with facilities on a case-by-case basis or upon request. Because Nevada uses CMS claims data to identify the incidence of HACs, it compares that information with the data contained in the sentinel event registry for an individual facility and contacts the facility if there is a discrepancy. The facility is asked to investigate the discrepancy and report back to the sentinel event registry.

Public Reporting: Nevada produces an aggregated-level sentinel event summary report on an annual basis. The reports include the total number sentinel events that occur across all medical facilities as well as a breakdown of the event types. It also provides information regarding the medical facilities' patient safety plans and patient safety committees. The decision for Nevada to publicly report adverse event and other health care quality information was prompted by consumer demand and the desire from patients to know how facilities perform on patient safety. Occasionally, the Division of Health receives feedback from patients and consumers, but overall the amount of feedback has been limited to date. Responses to concerns are handled by directly contacting the individual making a complaint. At this time there is no formalized process for responding to identified public concerns.

In June 2011, Nevada signed legislation that requires medical facilities to provide patients with information on how hospital infections are prevented, to publicly post information

on infections acquired in the facility, and designate an infection control officer. Since January 2012, the Division of Health has received some inquiries from the public about this legislation. Nevada officials contend that a national database could be used to compare data and information between States given that the methodology for collecting the data would be consistent. In addition, there would then be comparable numbers to make more comparisons between States.

4.5 Pennsylvania

Although most States mandate facilities to report HACs and other adverse events into State health departments, Pennsylvania's Medical Care Availability and Reduction of Error Act, otherwise known as "MCare," authorized the Patient Safety Authority (the Authority) to serve as the agency to operate a reporting system. The Authority is an independent State agency established under the law, enacted in 2002, with the support of Pennsylvania hospitals. Its primary functions include data collection, data analysis, guidance, education, and training.

Event Types: Facilities use a classification system, or taxonomy, to characterize the occurrence they report. The Pennsylvania Patient Safety Reporting System (PA-PSRS) classifies event types into the following major event types:

- Medication errors
- Adverse drug reactions
- Equipment, supplies, or devices
- Falls
- Errors related to procedures, treatments, or tests
- Complications of procedures, treatments, or tests
- Transfusions
- Skin integrity
- Other/miscellaneous

The categories above can be further broken down into second- and even third-level categories. For example, falls includes a series of subcategories including "falls while lying in bed," "falls while ambulating," "falls in the hallways," and "other types of falls." The complete Event Type Dictionary is a three-level taxonomy with 217 distinct Event Types. All 10 categories of Medicare HACs are included in this event-type dictionary, and the Authority has received event reports on each of the Medicare HACs since the beginning of its existence.

Data Collection and Analysis: All hospitals, birthing centers, and ambulatory surgical facilities must report "serious events" (actual adverse events) and "incidents" ("near-misses") to the Authority through the statewide, confidential Web-based reporting system known as the PA-PSRS. Pennsylvania was the first State in the nation to require the reporting of both serious

events and incidents. After a successful test phase, mandatory reporting was implemented in three phases across the State in 2004. In 2009, as the result of legislation enacted in July 2007, the Authority began collecting health care associated infections from more than 720 Pennsylvania nursing homes through an upgraded PA-PSRS system. To date, the Authority has received more than 1.3 million events collected in its database.¹

Because PA-PSRS is a secure system, it permits health care facilities to submit confidential reports. By law, reports should not contain any identifiable information, and no information about individual patients and providers is required or requested. In addition, no information about individual facilities is made public. The State of Pennsylvania operates other complaint and error reporting systems meant for individuals, where the Department of Health can issue sanctions and penalties, including fines and forfeiture of license, to health care facilities as appropriate. All incident reports are submitted by facilities through a process identified in their patient safety plans, as required by the MCare Act. However, the Act provides for one exception to this facility-based reporting requirement. Under this exception, a health care worker who feels his or her facility has not complied with reporting requirements may submit an anonymous report directly to the Authority.

In submitting a report, acute-care facilities (including hospitals, ambulatory surgery centers, birthing centers, and abortion facilities) respond to 21 core questions through check boxes and free-text narrative. To access PA-PSRS, facilities need only a computer with Internet access. The process is similar for nursing homes, which began reporting HAIs in June 2009, with the system posing different questions depending on what type of infection is reported. Questions answered by the facilities include those related to limited demographic information (such as a patient's age and gender), the location within a facility where the event took place, the type of event and the level of patient harm, if any. In addition, the report collects considerable detail about "contributing factors," details related to staffing, the workplace environment, and management and clinical protocols. The facility is also asked to identify the root cause of a serious event and to suggest procedures that can be implemented to prevent a recurrence.

Data Validity: The Authority's clinical team analyzes submitted reports for clinical validation and determines the extent, if any, of intervention needed with facilities. This team includes professionals with degrees and experience in medicine, nursing, law, pharmacy, health administration, risk management, product engineering, and statistical analysis, among other fields. In addition, the Authority has access to a large pool of subject matter experts in virtually every medical specialty. After the system electronically receives and prioritizes each report, the clinical team performs reviews, analysis, and, at times, follows up with individual facilities. The team's primary role is to identify situations of immediate jeopardy and to identify trends or improvements that can be implemented to improve patient safety.

¹ PA-PSRS was developed under contract with ECRI Institute, a Pennsylvania-based independent, nonprofit health services research agency, in partnership with HP, a leading international, information technology firm, and the Institute for Safe Medication Practices (ISMP), also a Pennsylvania-based, nonprofit health research organization.

Patient Safety and Quality Improvement Initiatives: The Patient Safety Authority then analyzes and evaluates the reports to make recommendations for changes in health care practices and procedures to reduce the number and severity of serious events and incidents. As a result of this comprehensive analysis, the Authority issues *Patient Safety Advisories* based on data submitted through PA-PSRS, supplemented by a scholarly search of the medical and clinical literature. *Advisory* articles are directed primarily to health care professionals for use by both clinical and administrative staffs. The Authority encourages these providers to use the articles as learning tools for patient safety and continuous quality improvement. The authority has issued advisories on a wide range of patient safety and health care quality topics, including the use of color-coded patient wristbands, infection control, radiation therapy, patient falls, wrong-site surgeries, and insulin doses. The advisories share successful models being used by hospitals and other health care providers at the State and national levels. Primary distribution of the *Advisories* is through e-mails, enabling the Authority to circulate the *Advisories* to thousands of individual health care providers, hospitals, and government and health care organizations around the world, including national patient safety and quality improvement organizations. As a result, the Authority is able to generate considerable interest in Pennsylvania's approach to promoting patient safety and in the lessons learned through the PA-PSRS system.

Another component of the PA-PSRS system is the set of analytical tools available to reporting facilities. These tools provide patient safety, quality improvement, and risk managers with detailed reports analyzing data related to their specific facilities. Many reports can also be exported to other software programs for inclusion in facility publications or in reports and presentations to trustees and senior management. In addition, facility personnel have the ability to export all, or any portion, of their facility's data. Managers can use this information for their internal quality improvement and patient safety activities. These analytical tools are an essential component of patient safety improvement efforts in Pennsylvania. Whereas the PA-PSRS system allows the Authority to focus on analyzing statewide aggregate data, the analytical tools within the system provide immediate, real-time feedback to individual facility managers helping them identify trends and actual or potential adverse patient outcomes within their institutions.

In 2007, the Authority developed a Patient Safety Liaison (PSL) program to provide Pennsylvania hospitals with consultants to help them improve patient safety in their facilities. PSLs are located in one of six regions of the State, and on a daily basis the Authority receives information through PSL consultants, which helps facilities break down barriers and create working environments that are conducive to a culture of safety. Through the PSL collaboration, the Authority is working with facilities on the following collaborative topics: mislabeled specimens, wrong-site surgery, falls, CLABSI, SSIs, and patient safety training for executive management and boards of trustees.

Public Reporting: The PSA's primary means of publicly reporting its collected data on patient safety events and Medicare HACs is posting an annual report on its Web site. These annual reports provide a comprehensive description of the Authority's primary activities, accomplishments, and aggregate data from facility reports with some trends and other descriptive statistics. Hospital or facility-level data are not reported publicly in Pennsylvania because the MCare Act ensured provider confidentiality. Aggregated data are provided for report volume, patient demographics, and patterns or trends in facility reports. The Executive Summary in the

2011 Annual Report, for example, provides highlights of data submitted to the PSA; and the data collection and analysis section reports the number and percentages of event types, including stratifications by serious events and incidents. Graphs are provided to show report submission trends over a 7-year period, and bar charts depict regional differences by event types and number of facility reports submitted.

A more recent addition to the PSA's annual reports is data and statistics on HAIs. Pennsylvania hospitals are mandated to conduct continuous surveillance for HAIs in all patient care areas using the NHSN for reporting, using all components of the NHSN Patient Safety Module. This requires facilities to report on the three HAIs that are part of the Medicare HACs, including CAUTI, vascular central-line infections or CLABSI, and certain SSIs. The Pennsylvania Department of Health is responsible for assessing the HAI data in NHSN to ascertain the patterns of HAIs in the annual report facility-specific rates of HAIs, to determine HAI trends by institution, and compare the State's rates with those seen elsewhere in the country. The PSA's annual report provides a summary of statewide results, in aggregate, of the Department of Health's analysis of HAI data via the NHSN.

[This page intentionally left blank.]

SECTION 5 DISCUSSION AND CONCLUSION

5.1 The Role of Recent Federal Initiatives for State Reporting and Nonpayment of Health Care–Acquired Conditions

5.1.1 *Hospital Compare* Reporting of Medicare Hospital-Acquired Conditions

CMS’ Hospital Compare is now publicly reporting facility-level rates for 8 of the 10 Medicare hospital-acquired conditions (HACs), which include foreign object retained after surgery, air embolism, blood incompatibility, Stages III and IV pressure ulcers, falls and trauma, manifestations of poor glycemic control, catheter-associated urinary tract infection (CAUTI), and vascular catheter-associated infections. Surgical site infections (SSIs) and deep vein thrombosis/pulmonary embolism are currently not included in this list that is reported on Hospital Compare. According to the Hospital Compare Web site, the reporting system “shows certain injuries, infections, or other serious conditions that patients with Original [fee-for-service] Medicare got while they were in the hospital” (CMS, 2012). The Web site acknowledges that some HACs are conditions that are rare and if they ever occur, hospital staff should identify and correct the problems that caused them. The rates are per 1,000 patient discharges, and there is no risk adjustment to account for the different kinds of patients treated at different hospitals. For this reason, CMS cautions that the reported rates should not be used to compare one hospital with another.

5.1.2 Recent Federal Laws and State Expansion of the National Healthcare Safety Network for Healthcare-Associated Infections (HAIs)

The Patient Safety Act of 2005: This Federal law named Patient Safety Organizations (PSOs) as the collectors of confidential, voluntarily reported patient safety events. These PSOs are also intended to be patient safety experts for health care providers and were charged with using the data they gather in the development of strategies to improve patient safety. For its part, Health and Human Services (HHS) was directed to develop a list of PSOs and a network of patient safety databases to collect the data into a central location. PSOs are located throughout the United States and can operate nationwide regardless of their home State.

We are still in the early stages of PSOs, which is why the Government Accountability Office (GAO) concluded that it is still too early in the process to evaluate their effectiveness (GAO, 2010). As GAO suggests, this may result from the absence of a specific deadline for developing these systems. It is quite possible that facilities are making preparations or are already providing data to the PSOs on certain conditions from the Medicare list of selected HACs, but we were unable to confirm this finding because of the strict confidentiality protections and the voluntary basis on which these data are reported. It will be important to continue monitoring the implementation of PSOs within the States and to consider the role these organizations play in the voluntary reporting of HAC data.

The HAI Recovery Act initiative: This Federal initiative—funded by the 2009 American Recovery and Reinvestment Act and being implemented by the Centers for Disease Control and Prevention (CDC)—prompted a large expansion of State-level reporting of HAIs. Although

some States were already collecting data on at least one HAI through National Healthcare Safety Network (NHSN) or a State-based reporting system, the Recovery Act uses both monetary and technical support to give all 50 States, the District of Columbia, and Puerto Rico the opportunity to, at a minimum, build and sustain programs to prevent HAIs. States may also opt to expand surveillance through NHSN reporting and create an HAI coordinator to manage day-to-day operations. Furthermore, States may opt to create, and serve as the lead organization of, prevention collaboratives. One of the primary goals of the Recovery Act for HAIs is to strengthen collaboration between State health departments, health care facilities, Federal HHS agencies, and other stakeholders, including clinicians, payers, and consumers to ultimately prevent infections and reduce deaths. The number of States that mandate the use of the NHSN for surveillance of HAIs is likely to increase as these HAI prevention programs are implemented and gain traction among key State leaders and policymakers. For this Update, we found 6 additional States that now mandate the use of NHSN, which brings the total to 27 States and the District of Columbia.

Mandatory HAI reporting on the Federal level began in 2011 for two HAI measures: (1) central line-associated bloodstream infection (CLABSI) and SSI. Per the final Inpatient Prospective Payment System (IPPS) rule published August 16, 2010, CLABSI reporting began in 2011, and SSI reporting will begin later in 2012. Both measure sets will be used for the fiscal year (FY) 2013 payment determination for acute-care hospitals paid under the IPPS (CMS, 2010). Hospitals will be required to use the NHSN as the data collection system, and results will be publicly reported via Hospital Compare at a future date.

Patient Protection and Affordable Care Act: Popularly known as the Health Care Reform law or Affordable Care Act, signed into law in March 2010 by President Obama, the law's intent is to improve the quality and efficiency of health care. Title III, Part I, Section 3001, requires that the Secretary of HHS establish a value-based purchasing program in which incentives will be paid to hospitals each fiscal year, beginning in FY 2013, on the basis of established performance standards to be selected by the Secretary (Affordable Care Act, 2010). Establishment of the standards will consider practical experience with the measures involved, historical performance standards, improvement rates, and opportunity for continued improvement. Hospitals will receive value-based incentive payments on the basis of their performance regarding at least five conditions or procedures: acute myocardial infarction, heart failure, pneumonia, surgeries, and HAIs. The value-based purchasing incentives will also be based on hospital scores on the Hospital Consumer Assessment of Healthcare Providers and Systems. Distribution of payments will be based on performance, with the highest-performing hospitals receiving the highest value-based incentive payment. Information on a hospital's performance will be publicly available on the Hospital Compare Web site. Efficiency measures will also be added to the value-based purchasing program in FY 2014 or in subsequent years.

The law also provides an annual fiscal year payment adjustment to qualifying hospitals as an incentive for reducing HACs beginning with FY 2015. Inpatient hospitals with high HAC rates will have the amount of payment for all discharges reduced to 99 percent of the amount of payment that would otherwise apply. This reduction will be applied to hospitals that are in the top quartile relative to the national average of HAC rates during the applicable period as

determined by the Secretary of HHS. The Secretary will be required to establish and implement an appropriate risk adjustment methodology.

The law also requires the Secretary to conduct a study of expanding HAC regulations to other facilities under the Medicare program under Title XVIII of the Social Security Act, including rehabilitation hospitals, long-term care hospitals, hospital outpatient departments, other hospitals excluded from the IPPS (cancer, children's, and Maryland waiver), skilled nursing facilities, ambulatory surgical centers, and health clinics. The study will include an analysis of the impact of such policy on the quality, safety, and cost of care under the Medicare program. A report to Congress on the results is to be submitted later in 2012. Although no Federal mandate in the legislation requires reporting of HACs, these provisions of the law heighten the awareness of the need for stronger patient safety protections in health care facilities, and more States may consider legislative acts or regulations that establish mandatory or voluntary reporting systems in response to Federal action.

5.2 Conclusion

In the absence of a nationally based mandated reporting system for medical errors and patient safety events, State-based reporting systems serve a significant role in collecting and reporting data for the Medicare HACs. More than two-thirds of States track at least one HAC (35 States and the District of Columbia); 28 of those States and the District of Columbia track at least one infection from the Medicare list of HACs through the NHSN. These systems appear to have great variability in terms of which events are tracked, the reporting criteria, and other information accompanying the report, such as the requirement for the facility to perform root cause analyses or to report near-misses. Despite these inconsistencies across States, there are common traits among State reporting systems. States use data in similar ways to improve patient safety and employ quality improvement programs within health care facilities. Most of the States also provide public reports; data are provided in aggregate to protect individual facilities from potential litigation or sanctions of medical professionals. Also, only one State with a State reporting system collects the event data on a voluntary basis. All other States with a reporting system have mandates in place to collect the data. Below is a summary of some of our key findings from conducting a more in-depth assessment of the four selected States (California, Connecticut, Nevada, and Pennsylvania):

- All four States recently expanded their list of HACs and other adverse events on which they are collecting data. It appears that the HAC payment policy has had some effect on State decisions to do so, as States examine what conditions are of national importance in terms of Medicare or Medicaid payment policy and quality reporting.
- Increasing importance is placed on data accuracy and validity, particularly in terms of clinicians reviewing incident reports or collected data on HACs.
- These States appear to be expanding or developing technology (e.g., computer-based) systems and Web portals to collect and share data. Consequently, there is a movement to have State adverse event data be more transparent to providers, insurers, patients, and consumers through different levels of public reporting.

- Public reporting of quality data continues to evolve. The level of reporting continues to vary across States, but two of the States we assessed more in-depth are transitioning from aggregate to facility-level reporting of HAC data (Nevada and Connecticut).
- Consumers and the public are beginning to pay more attention or access publicly available quality data. It will be interesting to see how this evolves as consumers and patients become more knowledgeable about what's available and how the information affects them.
- Some States have developed specific State-based quality improvement teams (preventionists) to collaborate with facilities to improve care processes and outcomes for specific HACs. This is particularly true for HAIs.
- There is some movement, particularly in California, to link process data (CLIP) with outcome data (CLABSI) to analyze the connection between process improvement and outcome improvement.
- Among the four States we interviewed, there was interest for a national database that uses standardized definitions and data collection methods, can be used for comparisons within State across facilities and across States, and reports an aggregate national rate on selected adverse events.
- States with reporting systems appear to be committed to improving patient safety within their health care facilities, and provide patients and consumers with more information on the quality of care being provided.

Current Federal initiatives have bolstered HAC reporting activities at the State level, yet there are still overriding concerns surrounding the variability and lack of standardization across State reporting systems. These differences make it unsuitable to identify national incidence and trends for HACs. Reporting formats vary substantially from State to State; underreporting of HAC data makes it problematic to make any significant inferences or to track improvement over time. The passage of the Affordable Care Act did not mandate or provide national guidelines for reporting systems to collect more standardized information on HACs, but the law calls for stronger patient safety protections in health care settings. In our estimation, more States may take action, as a result, to implement reporting systems for patient safety events. However, it is unclear whether States will take a more regulatory approach or will encourage more voluntary reporting initiatives through PSOs or other State-based or regional collaborative.

REFERENCES

- California Department of Public Health (CDPH): *Central Line Associated Blood Stream Infections (CLABSI)*. Accessed January 6, 2012. Available from <http://www.cdph.ca.gov/programs/hai/Pages/CentralLineAssociatedBloodstreamInfections-CLABSI-Reports.aspx>.
- California Hospital Association (CHA): Hospitals called on to participate in event and reporting project. February 5, 2012. Accessed March 12, 2012. Available from <http://www.calhospital.org/general-information/hospitals-called-participate-event-and-reporting-project>.
- Centers for Disease Control and Prevention (CDC): <http://www.cdc.gov/ncidod/dhqp/pdf/ar/MDROGuideline2006.pdf>, 2006. Accessed June 1, 2011.
- Centers for Medicare & Medicaid Services (CMS): Hospital Compare. Accessed March 14, 2012. Available from <http://www.hospitalcompare.hhs.gov/>
- Centers for Medicare & Medicaid Services (CMS): Medicaid Program: Payment adjustment for provider-preventable conditions including health care-acquired conditions. Federal Register 76 (33): 9283-9295, February 17, 2011.
- Centers for Medicare & Medicaid Services (CMS): Medicare Program: Hospital inpatient prospective payment systems for acute care hospitals and the long term care hospital prospective payment system changes and FY2011 rates. Final Rule. Federal Register 75 (157): 50200-50202, 2010.
- Centers for Medicare & Medicaid Services (CMS): Medicare national coverage determinations manual. Chapter 1, Part 4 (Sections 200–310.1), Coverage Determinations. Accessed February 2011. Available from https://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf
- Centers for Medicare & Medicaid Services (CMS): Medicare Program: Hospital inpatient prospective payment systems for acute care hospitals and the long term care hospital prospective payment system changes and FY2008 rates. Final Rule. Federal Register 72: 4700-47217, August 22, 2007.
- Government Accountability Office (GAO): Patient Safety Act: HHS is in the process of implementing the act, so its effectiveness cannot yet be evaluated. Pub. No. GAO-10-281. Washington, DC. U.S. Government Accountability Office (GAO), January, 2010. Accessed June 14, 2010. Available from <http://www.gao.gov/new.items/d10281.pdf>.
- Hanscom, R.B., Mello, M., Powers, R.B., et al.: Legal liability and protection of patient safety data. Commissioned paper for the Institute of Medicine Committee on Patient Safety Data Standards, 2003.

Institute of Medicine (IOM): To err is human: Building a safer health care system. Washington, DC. National Academy Press, 2000.

Leape, L.L., and Berwick, D.M.: Five years after To err is human: What have we learned? JAMA 293(19):2384-2390, May 2005.

Mello, M., Kelly, C.N., and Brennan, T.A.: Fostering rational regulation of patient safety. Journal of Health Politics, Policy and Law, 30(3):375-426, June 2005.

National Academy for State Health Policy (NASHP): Patient safety toolbox. 2010. Accessed June 14, 2011. Available from <http://www.nashp.org/pst-welcome>.

National Quality Forum (NQF): Serious reportable events in healthcare: A consensus report. Washington, DC. National Quality Forum, 2002.

National Quality Forum (NQF): Serious reportable events in healthcare 2006 update. Washington, DC. National Quality Forum, 2006.

Office of Inspector General (OIG): Adverse events in hospitals: State reporting systems. Washington, DC. U.S. Department of Health and Human Services, 2008.

Office of the Assistant Secretary for Health: National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination. 2012. Accessed May 3, 2012. Available from <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

Patient Protection and Affordable Care Act (Affordable Care Act). P.L. 111-148. Washington, DC. U.S. Government Printing Office, 2010. Accessed June 14, 2011. Available from http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf.

Rosenthal, J., and Takach, M.: Guide to state adverse event reporting systems. Portland, ME. National Academy for State Health Policy, 2007.

United States Census. 2010 Census Data. Accessed March 9, 2012. Available from <http://2010.census.gov/2010census/data/>.

APPENDIX A
MEDICARE LIST OF HOSPITAL-ACQUIRED CONDITIONS

The CMS list of HACs is divided into 10 categories. Effective October 1, 2008, CMS reduces payment for hospitalizations complicated by these categories of conditions that were not present on admission (POA).

Hospital-Acquired Condition

1. Foreign object retained after surgery*
2. Air embolism*
3. Blood incompatibility*
4. Pressure ulcers (stages III and IV)*
5. Falls*
 1. Fracture
 2. Dislocation
 3. Intracranial injury
 4. Crushing injury
 5. Burn
 6. Other injuries
6. Manifestations of poor glycemic control*
 1. Hypoglycemic coma
 2. Diabetic ketoacidosis
 3. Nonketotic hyperosmolar coma
 4. Secondary diabetes with ketoacidosis
 5. Secondary diabetes with hyperosmolarity
7. Catheter-associated urinary tract infection
8. Vascular catheter-associated infection
9. Deep vein thrombosis/pulmonary embolism associated with
 1. Total knee replacement
 2. Hip replacement
10. Surgical site infection
 1. Mediastinitis after coronary artery bypass graft
 2. Associated with certain orthopedic procedures involving the
 1. Spine
 2. Neck
 3. Shoulder
 4. Elbow
 3. Associated with certain bariatric surgical procedures for obesity
 1. Laparoscopic gastric bypass
 2. Gastroenterostomy
 3. Laparoscopic gastric restrictive surgery

*One of the NQF's 28 SREs in health care.

SOURCE: Fiscal Year 2009 Final Inpatient Prospective Payment System Rule, 73 Fed. Reg. 48434, 48471 (August 19, 2008).

[This page intentionally left blank.]

APPENDIX B
NATIONAL QUALITY FORUM LIST OF SERIOUS REPORTABLE EVENTS

Surgical Events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately post-operative death in an ASA Class 1 patient

Product or Device Events

- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- Patient death or serious disability 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 disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient elopement (disappearance)
- Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

Care Management Events

- Patient death or serious disability 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 disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility

- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy
- Artificial insemination with the wrong donor sperm or wrong egg

Environmental Events

- Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

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 of any age
- Sexual assault on a patient within or on the grounds of the healthcare facility
- Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility

APPENDIX C
IN-DEPTH REVIEW DISCUSSION TOPIC

The following are questions for State officials that cover the following four domains of inquiry: data utilization, data validity, quality improvement, and public reporting.

Data Utilization

1. What is the intent of your reporting system?
 - a. Has the intended use changed over the years? If so, how?
2. Validate the HACs the State is collecting data on. (This could include previously considered HACs as well.)
3. How is the State utilizing the collected data?
 - a. Reporting only (public, regulatory, government, hospitals, hospital association, CDC through NHSN)
 - b. Quality Improvement (e.g., clinical care practices, systems improvement, formation of collaboratives)
 - i. Inquire about specific quality improvement initiatives (who is involved and how is it operated?)
 - c. Are the data being shared with other entities (State agencies, participating facilities, PSOs) in your State or across States? Are there any data collaboratives?
4. What data disclosure or protection practices are in place?

Data Validity

Is there a mechanism for auditing the data for accuracy and validity?

- a. If so, how are the data audited (what type of review: clinical, on-site, root cause analysis, or other)?
- b. What if anything are you finding from the auditing process that you are able to share?
- c. Who receives or reviews the audited data?
- d. Is there a mechanism to address issues with the data beyond verifying their accuracy or validity? Are you able to share that information?

Quality Improvement

1. For those entities that are implementing the data for quality improvement; what outcomes are you seeing from your strategies?
2. Has the reporting of HACs had an impact on how hospitals and agencies are responding to identified quality issues?
3. To what extent are you sharing event-level data with providers for quality improvement purposes?

Public Reporting

1. How is the information publicly reported (individual events, facility specific, statewide-aggregate)?
2. What, if any, response have you had from the public regarding publicly reported HACs?
 - a. What kinds of questions are you receiving?
3. Probe: Is the public questioning the data validity or any concerns with patient confidentiality of the data?
4. What is your opinion about the feasibility of creating a national database for collecting adverse medical events specific to the HACs?
 - a. How would you view using a national database of this kind?