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Update on State Government Tracking of Health Care-Acquired Conditions

FINAL

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ACRONYMS USED IN THIS REPORT

AHRQ—Agency for Healthcare Research and Quality
CAP—corrective action plan
CAUTI—catheter-associated urinary tract infection
CC—comorbidity or complication
CDC—Centers for Disease Control and Prevention
C-diff—*Clostridium difficile*
CLABSI—central line-associated bloodstream infections
CMS—Centers for Medicare & Medicaid Services
DVT—deep vein thrombosis
GAO— Government Accountability Office
HAC—hospital-acquired conditions
HAC-POA—Hospital-Acquired Conditions–Present on Admission program
HAI—health care-associated infection
HCAC—health care-acquired conditions
HHS—U.S. Department of Health and Human Services
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 Determinations
NHSN—National Healthcare Safety Network
NPRM—notice of proposed rulemaking
NPSD—network of patient safety databases
NQF—National Quality Forum
OIG—Office of Inspector General
PSO—patient safety organization
RCA—root cause analysis
SRE—serious reportable event
VAP—ventilator-associated pneumonia

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EXECUTIVE SUMMARY

Objective

To provide an update report on the status of State government tracking of health care-acquired conditions (HCACs).

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 Conditions—Present on Admission (HAC-POA) program, whereby inpatient prospective payment system cases can no longer be assigned to higher-paying Medicare severity diagnosis-related groups on the basis of preventable complicating conditions that are acquired during the hospital stay. CMS identified 10 HACs as being preventable under accepted guideline-consistent care and targeted these for application of the HAC-POA payment policy. CMS contracted with RTI International to evaluate the HAC-POA program. 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.

This report provides the first annual update to the *State Government Tracking of Hospital-Acquired Conditions Report* prepared in June 2010. That 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. For this update (Task 8.3), we identify changes and additions in State governments' roles to track and report HCACs and other adverse events. In addition, we describe 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 proposed rule would implement 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). 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.

Key Findings

As of February 2011, 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, with New Hampshire the most recent (2010).

There are currently no Federal standards for State reporting systems and no uniform list of reportable events or HCACs. States are free to designate which events are

reportable, but *harm* is a common denominator for reporting. However, beginning in July 2011 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.

The majority of States publicly report only aggregate-level data on HCACs. Only six States report both aggregate and facility-specific HCAC data through adverse event reporting systems; five States do not offer any public reporting.

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

Currently, 16 States use data collected from adverse event reporting systems for both regulatory and quality improvement purposes. Data for quality improvement are used to communicate with other organizations about best practices and patient safety to enhance organizational learning and to improve processes of care.

In 32 States, reporting of health care-associated infections is mandated. Of these States, 22 use or will use the National Healthcare Safety Network 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 half the States track at least one Medicare HAC (31 States and the District of Columbia). States vary widely as to the total number of HACs tracked through a State-based reporting system—for example, 12 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.

In 15 States and the District of Columbia, the State collects at least six Medicare HACs. Nevada collects data on all 10 HACs.

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. The States 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 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.

SECTION 1 INTRODUCTION

1.1 Brief Background on the Medicare Hospital-Acquired Conditions–Present on Admission Program and the Role of States in Tracking and Reporting Adverse Events and Other Medical Errors

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 application of evidence-based guidelines. In response to the Act, the Centers for Medicare & Medicaid Services (CMS) developed the Hospital-Acquired Conditions–Present on Admission (HAC-POA) program, whereby inpatient prospective payment system (IPPS) cases can no longer be assigned to higher-paying MS-DRGs on the basis of preventable complicating conditions that are acquired during the hospital stay. The IPPS is a system of payment for the operating costs of acute-care hospital inpatient stays under Medicare Part A (hospital insurance) based on prospectively set rates.

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-POA payment policy. CMS has contracted with RTI International to evaluate the HAC-POA program. 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 landmark *To Err Is Human*, released in 2000, called for a nationwide public mandatory reporting system to identify and learn from medical errors and other adverse events (Institute of Medicine [IOM], 2000). 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 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 2000 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 legislative acts to encourage and fund voluntary reporting systems and other patient safety initiatives. In 2003, CDC's Healthcare Infection Control Practices Advisory Committee published guidance to States for implementation of health care-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 by facility of HAI rates 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 with 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 that patient safety data contained in reporting systems are 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, the Agency for Healthcare Research and Quality (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 will support programs to boost surveillance and prevention of HAIs, encourage collaboration, train the workforce in HAI prevention, and measure outcomes. These efforts are consistent with the recommendations outlined in the *HHS Action Plan to Prevent Health Care–Associated Infections* (Office of Assistant Secretary for Health, 2009). 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 22 States require or will require hospitals to report HAIs using NHSN.

Table 1-1 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 1-1
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: <u>Hospital-Acquired Conditions (HAC) and Present on Admission Indicator</u> . Available from http://www.cms.gov/HospitalAcqCond/
Health care–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: <u>HHS Action Plan to Prevent Healthcare-Associated Infections: Executive Summary</u> . (n.d.) Available from http://www.hhs.gov/ash/initiatives/hai/exsummary.html

(continued)

Table 1-1 (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: MS-DRG, Medicare Severity Diagnosis-Related Group; CLABSI, central line-associated bloodstream infection; VAP, ventilator associated pneumonia; CAUTI, catheter-associated urinary tract infection; NPRM, notice of proposed rulemaking.

1.2 Changes in Approach for the Updated (Year 2) Study on State Government Tracking of Health Care-Acquired Conditions (HCAC)

The purpose of Task 8.3 is to update our study on State government tracking of health care-acquired conditions. For Task 4.3, we conducted a comprehensive inventory of State tracking activities for HACs and reported our findings in the Task 4.3 Report—*State Government Tracking of Hospital-Acquired Conditions*. For this report, our approach was two-fold: (1) to investigate whether States with adverse event reporting systems made major changes to their reporting system requirements or added any current or previously considered Medicare

HACs to their sentinel or adverse event reporting list, and (2) to describe States' Medicaid regulatory requirements to adjust payment for HCACs and provide a snapshot of which States have already implemented Medicaid HCAC policies.

1.3 Organization of the Report

In the following sections of this report, we present our methodological approach to identifying and summarizing State tracking systems for HCACs (*Section 2*), the results of our document review of State tracking materials to provide an update (*Section 3*), and a discussion of the role of the recent Federal initiatives, including the Patient Protection and Affordable Care Act, for State tracking of HCACs (*Section 4*).

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SECTION 2 METHODOLOGY

2.1 Data Collection Approach

Our data collection approach for the update report entailed the following: (1) a thorough document review of existing State tracking reports, databases, and other sources; (2) collection and review of publicly available State reports that provide data on health care-acquired conditions (HCACs); and (3) informal contacts with State personnel to verify document reviews.

2.1.1 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 is derived from several sources, including recent 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 health care-associated infection (HAI) reporting systems and the role of the Patient Safety Act also informed our document review activities. 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 HCAC data.

2.1.2 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 (SRE) 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 Limitations

The information in this report reflects our findings from the aforementioned document review activities, discussions with Centers for Disease Control and Prevention (CDC) and Agency for Healthcare Research and Quality (AHRQ) staff, and contacts with select State personnel. We verified that our updates on State-level information already collected from NASHP and OIG are 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 HCACs. Future annual reports and updates on State tracking of HCACs that are part of this CMS contract to evaluate the HAC-POA program will help address these limitations. 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.

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SECTION 3 FINDINGS

3.1 Update on State Medical Error and Adverse Event Reporting Systems

Last year’s baseline report presented findings from our inventory of State governments’ medical error and adverse event reporting systems. Our selection of the 26 States and District of Columbia presented 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 2010, we discovered that New Hampshire (as shown in **Table 3-1**) recently enacted legislation to require the reporting of the National Quality Forum (NQF) Serious Reportable Events (SREs) occurring in hospitals and ambulatory surgical centers. This brings the total to 27 States and the District of Columbia with an adverse event or medical error reporting system authorized by State government. More details on New Hampshire’s reporting system will be forthcoming in the months ahead, but State legislation describes a nonpunitive system of reporting that will include the mandatory completion of root cause analyses and corrective action plans. The Health Commissioner will also be required to publish an annual report summarizing the adverse events of the past year, and he or she will be charged with recommending updates to the initial list of 28 NQF events to the legislature.

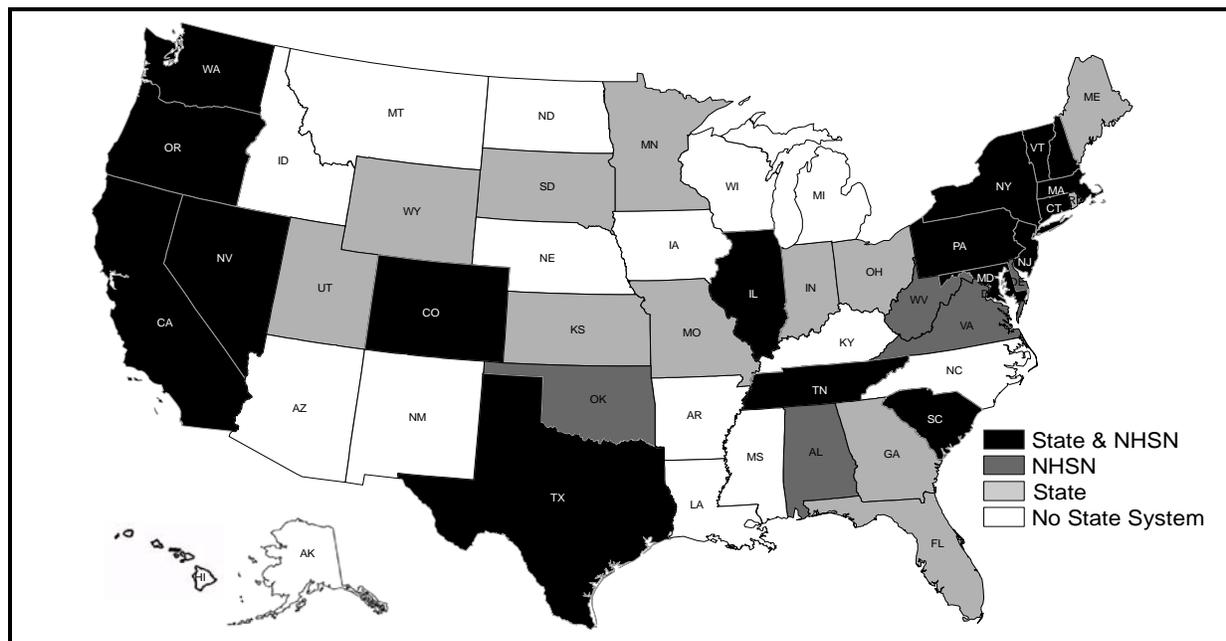
**Table 3-1
General characteristics of New Hampshire Adverse Event Reporting System**

State	Start date	Reportable event list	Data submission format	Facilities required to report
NH	Jan 2010	28 NQF Serious Reportable Events	Manual	General/acute-care hospitals and ambulatory surgical centers

NQF, National Quality Forum.

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. Beginning in 2011, 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 3-1** 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 3-1
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 health care–associated infections (HAIs). As the map illustrates, currently 17 States (California, Colorado, Connecticut, Illinois, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, and Washington) both maintain a State-based reporting system for medical errors and adverse events and track or will soon track HAIs through NHSN. The 5 States that track HAIs through NHSN, but do not have a State-based reporting system for medical errors and adverse events, are Alabama, Delaware, Oklahoma, Virginia, and West Virginia. Currently, 11 States (Florida, Georgia, Indiana, Kansas, Maine, Minnesota, Ohio, Rhode Island, South Dakota, Utah, and Wyoming) and the District of Columbia maintain a State-based reporting system and do not participate in NHSN. The remaining 16 States (Alaska, Arizona, Arkansas, Hawaii, Idaho, Iowa, Kentucky, Louisiana, Michigan, Mississippi, Montana, Nebraska, New Mexico, North Carolina, North Dakota, and Wisconsin) neither track HAIs through NHSN nor maintain a 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 32 States that have mandated reporting of HAIs, 22 use or will use NHSN. Alabama was the newest State to mandate NHSN use for HAI reporting in 2010. 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. Only device-associated infections are measured for bloodstream infections, urinary tract infections and pneumonia, along with surgical site infections associated with 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. Twenty States do not mandate reporting of HAIs or do not voluntarily report them; 6 of those States (Alaska, Arizona, Indiana, New Mexico, North Carolina, and Ohio) recently completed or have ongoing study committees considering whether to mandate HAI reporting. 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 in New Mexico. 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 HAI.

3.3 Other State-Based Patient Safety Reporting Initiatives

Many States do not require mandatory reporting of adverse events, nor is information on near-misses or potential medical errors systematically gathered by State governments. Nevertheless, the concern about patient safety and medical errors continues to receive attention across some States' entire continuum of health care. For this update report, we are highlighting States that have robust patient safety reporting activities that are not necessarily authorized by State government.

Michigan, for example, convened a State Commission on Patient Safety in 2006 to make a set of recommendations to the governor for a statewide voluntary, confidential, nonpunitive health care error and near-miss reporting system. In response to the Federal Patient Safety and Quality Improvement Act of 2005, the Michigan Hospital and Health Association established a Patient Safety Organization (PSO) that collects and analyzes data about medical errors and near-misses in Michigan hospitals. As of 2008, 108 hospitals had voluntarily committed to participating in a project called MHA Keystone: HAI Collaborative (MHA, 2010). The collaborative collects data on hospital-acquired infections starting with a strategic and manageable list of targeted infections. Interventions include a focus on reducing catheter-associated urinary tract infections (CAUTI) and avoiding CLABSI. Early results of the implementation of the CAUTI prevention bundle demonstrated significant results, and additional hospitals have implemented the care and removal intervention in recent months.

The MHA Keystone: HAI collaborative has become a model for protecting patients from infection and has been expanded to other States with distinct interventions under way for

CLABSI and CAUTI prevention. The MHA Keystone Center uses the Johns Hopkins University collaborative model for transformational change and is based on the “four E’s”: Engage, Educate, Execute and Evaluate. The activities supporting each step of the process vary by project but are always detailed and evidence based to ensure meaningful data and significant opportunity for change. At the heart of each collaborative is a focus on improving organizational culture using change principles and behavioral science. This intervention, called the Comprehensive Unit-based Safety Program (CUSP), integrates communication, teamwork, and leadership to create and support a “harm-free” patient care culture. Additionally, the initiative will begin a partnership to monitor and report *Clostridium difficile* (C-Diff)—a previously considered HAC—in the year ahead, supported by funding from the American Recovery and Reinvestment Act.

Nebraska is another State with a medical error reporting system that is set forth in its State Patient Safety Improvement Act (Nebraska DHHS, 2008). The Act allows certain patient safety organizations to collect data on a host of specified types of medical errors from health care providers that agree to participate. Participating providers voluntarily agree to report medical errors, prepare root cause analyses, and implement action plans. The Act is not administered by the State Department of Health and Human Services, and such reporting is not required of licensed health professionals. The Nebraska Coalition for Patient Safety comprises the five founding organizations and 37 member hospitals. The Coalition is governed by a 12- to 15-member board of directors that includes representation from each of the founding organizations plus at least one consumer member.

As we reported last year, the Government Accountability Office (GAO) found that it was still too early in the process to evaluate the effectiveness of PSOs (GAO, 2010). Located throughout the United States, PSOs can operate nationwide regardless of their home State. Facilities may well be preparing to provide or already provide data to PSOs on certain Medicare HACs, but we are unable to confirm this possibility because of the strict confidentiality protections and the voluntary basis on which these data are reported.

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

Table 3-2 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. About 3 out of 5 States track at least one HAC (32 States). 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. New Jersey legislation required the reporting of SSIs following coronary bypass graft surgery as of early 2010. Nevada added the following to its list of reportable events: foreign object retained after surgery, air embolism, DVT, and blood incompatibility.

Table 3-2
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	—
CA	State	State	State	State	State	State	—	NHSN	—	—
CO	—	—	—	State	State	—	—	NHSN	NHSN	State
CT	State	State	State	State	State	State	State	State, NHSN	State	—
DC	State	State	State	State	State	State	State	NHSN	—	—
DE	—	—	—	—	—	—	—	NHSN	—	—
FL	—	—	—	—	—	—	State	State	State	State
GA	—	—	—	—	State	—	—	—	—	—
IL	State	State	State	—	State	State	—	NHSN	NHSN	State
IN	State	State	State	State	State	State	—	—	—	—
ME	—	—	State	—	—	—	—	State	—	—
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
OK	—	—	—	—	—	—	—	NHSN	—	—
OH	State	—	—	State	—	—	—	State	State	—

(continued)

Table 3-2 (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
OR	State	—	State	State	State	State	—	NHSN	NHSN	—
PA	State	—	State	State	State	—	NHSN	NHSN	NHSN	State
RI	—	—	—	—	State	—	—	—	—	—
SC	—	—	State	—	State	—	—	NHSN	NHSN	—
TN	State	—	State	—	State	—	—	NHSN	NHSN	—
TX	State	—	State	—	—	—	—	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.

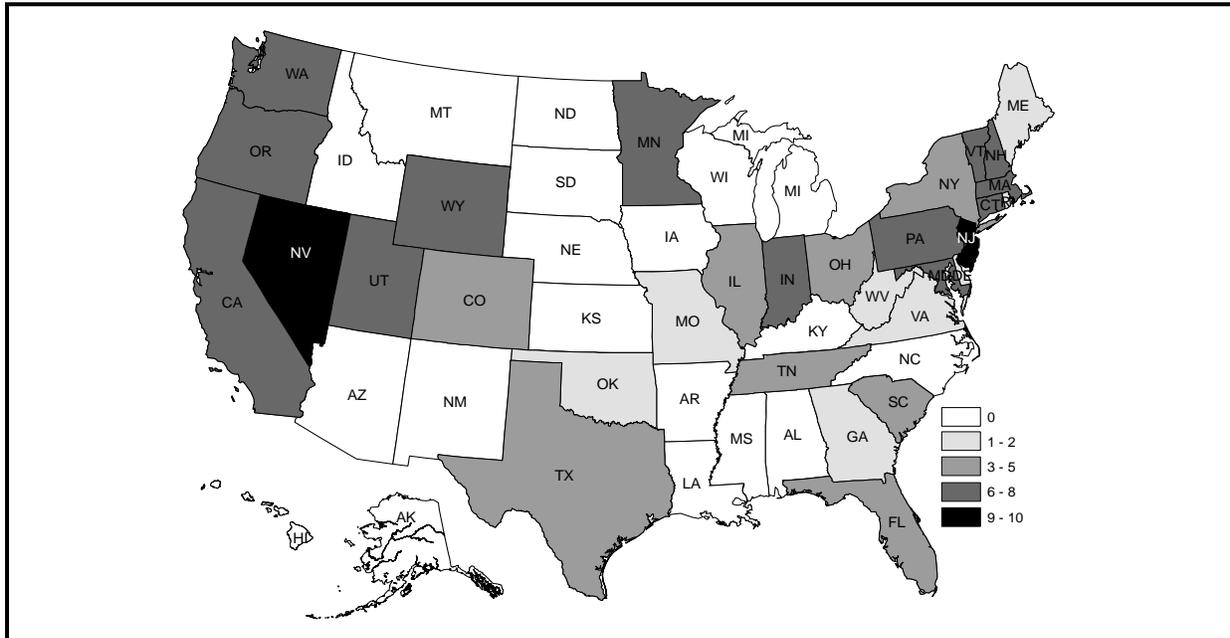
As previously noted, New Hampshire recently enacted legislation requiring the reporting of the 28 NQF serious reportable events. This brings to 15 the number of States that track all HACs that are part of the NQF's list of 28 SREs. These HACs include (1) foreign object retained after surgery, (2) air 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 have started or will soon finish a transition period during which HAIs will be tracked through the NHSN moving forward. Connecticut still tracks nosocomial infections that result in death or serious injury through its adverse event reporting system, while also mandating the reporting of CAUTI and CLABSI through the NHSN. A subset of vascular catheter-associated infections, CLABSI continue to be the HAIs most commonly required to be reported through NHSN, with 23 States that are requiring 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 14 States, whereas only 3 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. These plans were reviewed by CDC to help understand how State activities can contribute to the HHS HAI goals, identify gaps, and determine means of additional support. OHQ has since offered project funding to address some of these gaps.

The number of States collecting deep vein thrombosis/pulmonary embolism as part of their adverse event reporting system increased from three to six since our last report, with the addition of Colorado, Illinois, and Nevada. This HAC is an AHRQ-designated patient safety indicator, but the condition is not one of the 28 NQF SREs. 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 3-2* shows, New Jersey and Nevada are the only States that collect 9 to 10 categories of Medicare HACs (Nevada collects all 10 HACs). Eight States (Delaware, Georgia, Maine, Missouri, Oklahoma, Rhode Island, Virginia, and West Virginia) collect either 1 or 2. Another eight States (Colorado, Florida, Illinois, New York, Ohio, South Carolina, Tennessee, and Texas) collect between 3 and 5 HACs. Thirteen States plus the District of Columbia collect 6 to 8 HACs: California, Connecticut, District of Columbia, Indiana, Maryland, Massachusetts, Minnesota, New Hampshire, Oregon, Pennsylvania, Utah, Vermont, Washington, and Wyoming.

Figure 3-2
Number of Medicare-listed hospital-acquired conditions reported by States



3.5 Previously Considered Hospital-Acquired Conditions

For this update report, we conducted an inventory of the 28 States with adverse event reporting systems and States mandated to report HAIs through the NHSN to determine whether they track any of the seven previously considered HACs formerly known as candidate HACs.

These health care-acquired conditions include the following:

1. *Clostridium difficile* associated disease (C-Diff)
2. Delirium
3. Legionnaires' disease
4. *Staphylococcus aureus* septicemia
5. Methicillin-resistant *Staphylococcus aureus* (MRSA)
6. Iatrogenic pneumothorax
7. Ventilator-associated pneumonia (VAP)

These conditions were under consideration for the HAC-POA program but had limitations that did not meet the statutory requirements and therefore did not become part of the final approved 10 HACs. Four of the previously considered HACs fit the criteria for high volume and high cost: VAP, MRSA, C-Diff, and iatrogenic pneumothorax. One of the most prevalent issues was the lack of a unique ICD-9 CM code to distinguish the condition (e.g., VAP). Pneumonia has multiple codes that may or may not apply to beneficiaries who received

ventilator treatment. In addition, clinicians cited the difficulty in determining what constitutes VAP and the difficulty in preventing it.

Another issue is the availability of evidence-based guidelines (EBGs) and the degree to which the condition can be prevented through use of an EBG. For example, CDC and the Healthcare Infection Control Practices Advisory Committee published evidence-based infection prevention guidelines for multi-drug resistant organisms, including C-Diff, in 2006 (CDC, 2006). The National Guideline Clearing House also lists two EBGs for C-Diff: *Strategies to Prevent Clostridium Difficile Infections in Acute Care Hospitals* and *Clinical Practice Guidelines for Clostridium Difficile Infection in Adults: 2010 Update*, by The Society for Healthcare Epidemiology in America (SHEA) and the Infectious Diseases Society of America.

A third issue in considering these HACs for inclusion is to determine whether the condition can be reasonably prevented through the use of EBGs. According to current EBGs, colonization by MRSA is not a reasonably preventable condition, therefore MRSA does not meet the “reasonably preventable” statutory criteria for a HAC (CMS, 2007). However, MRSA is a high-volume/high-cost condition that has a prevention guideline that does meet the statutory criteria. It is a common bacterium both internal and external to the hospital environment, but it is a condition that does not have a comorbidity or complication (CC) nor a major comorbidity or complication (MCC) associated with it. There was also interest in including both MRSA and C-Diff because they are serious public health concerns. Although iatrogenic pneumothorax is a high-cost and high-volume condition, there is some concern about its preventability in some cases. **Table 3-3** shows which States have mandatory reporting of the Medicare list of previously considered HACs either through the NHSN or State Reporting System or through both. Five of the seven previously considered HACs, four of which are infections, are tracked in 18 of the States that have adverse event reporting systems. We did not find evidence that States track Delirium or Legionnaire’s Disease. MRSA, the most common previously considered HAC, is tracked in 12 States. Three additional States (Oregon, South Carolina, and Virginia) require facilities to complete a MRSA laboratory surveillance report, but there is no formal reporting system in place.

Oregon does not require MRSA reporting, but hospital laboratories are required to submit MRSA isolates to the Oregon State Public Health Lab for surveillance. South Carolina confines reporting to a laboratory-reportable condition, and Illinois limits reporting to intensive care unit patients. Another previously considered HAC that is frequently tracked by States is C-Diff, for which the condition is monitored in nine States. VAP is tracked in eight States either through NHSN or the State’s reporting system, and iatrogenic pneumothorax is tracked in three States. Minnesota, Pennsylvania, and Washington are the only three States that have mandatory tracking of Legionnaires’ disease. No evidence was found to suggest that States currently track the two remaining previously considered HACs (delirium and *Staphylococcus aureus*).

Table 3-3
State tracking of the Medicare list of previously considered hospital-acquired conditions

State	C-Diff	Iatrogenic pneumothorax	MRSA	VAP	Legionnaires' disease
CA	NHSN	—	NHSN and State	—	—
CT	—	—	State	—	—
FL	—	—	—	—	—
IL	State	State	State	State	—
ME	—	—	State	—	State
MN	State*	State*	State*	—	State*
MO	State	—	State	State**	—
NH	—	—	—	State	—
NV	—	—	NHSN	—	—
NJ	—	—	NHSN and State	—	—
NY	NHSN and State	State***	—	—	—
OH	State	—	State	—	—
OK	—	—	—	NHSN	—
PA	NHSN	—	—	NHSN	State
RI	—	—	—	—	—
SC	—	—	State	—	—
TN	NHSN and State	—	NHSN and State	State	—
TX	—	—	—	—	—
WA	—	—	State	NHSN	State

NOTE: A dash (—) signifies that the State does not track the condition; C-Diff, Clostridium difficile; MRSA, methicillin-resistant Staphylococcus aureus; VAP, ventilator-acquired pneumonia; 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

*Reported through the Minnesota Electronic Disease Surveillance System (MEDSS), which will be fully operational in early 2011 ** Reports presence of “Head of Bed at 30 degrees” versus VAP, which is a process measure for the VAP Care Bundle *** Iatrogenic pneumothorax is required to be reported under New York State Reporting Occurrence Code of Intravascular Catheter Related.

SOURCE: <http://www.cdc.gov/HAI/stateplans/HAIstatePlans.html>

3.6 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 HCACs. 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 shall not result in a loss of access to care or services for Medicaid beneficiaries.

During the course of our report preparation, the CMS Center for Medicaid and State Operations (CMSO) issued a survey to States to obtain information on current State Medicaid practices for prohibiting payments for HCACs. The survey is still undergoing the Paperwork Reduction Act process and has not been made mandatory. However, CMSO received information from a few States through the survey and reviewed information gathered from several sources, including State Plan Amendments (SPA), National Academy of State Health Policy, and individual States. Its intent is to incorporate effective State practices into Federal regulations regarding the prohibition of payments to States for HCACs.

According to CMSO's preliminary findings, 21 States have HCAC-related nonpayment policies. Thirteen of these State SPAs elected to use State plan authority to implement nonpayment policies. All of the SPAs implement policies that would protect the State from dual-eligible liability either by directly prohibiting payment for Medicare crossover claims or by relying on existing State plan authority to deny payment for claims previously denied by Medicare. CMSO found that 9 of the States (Connecticut, Florida, Indiana, Kansas, Massachusetts, Minnesota, New Jersey, New York, and Wisconsin) implemented Medicaid-specific policies that reduce payment for services provided to Medicaid beneficiaries. Five of these States (Connecticut, Florida, Indiana, Kansas, and Wisconsin) identify all of Medicare's list of HACs for nonpayment. These States employ Medicaid State plan language that would allow them to mirror subsequent changes in Medicare's list. Minnesota identifies only a portion of Medicare's current HAC list for nonpayment. New York has identified its own list of 14 "never" events and avoidable conditions that are a partial list of the NQF list of serious reportable events. New Jersey has identified two of Medicare's HACs along with one other condition and Medicare's national coverage determinations (NCD). Under these NCDs, Medicare does not cover a surgical or other invasive procedure to treat a particular medical condition when the practitioner erroneously performs any of the following: (1) a different procedure altogether; (2) the correct procedure but on the wrong body part; or (3) the correct procedure but on the wrong patient (CMS, 2011). Maryland identifies the most conditions, 50, which are a subset of 64 conditions identified as "possibly preventable conditions."

Similar variation exists in States' plan language identifying Medicare's NCD for nonpayment. Massachusetts has foregone the use of Medicare's current list of HACs altogether and elected to identify the three Medicare NCD along with the other 25 serious reportable events on the NQF list of serious reportable events. Additionally, Kansas identifies all three of Medicare's NCD for nonpayment, whereas Florida's plan language does not reference NCD at all. CMSO does note, however, that the nature of the NQF serious reportable events, such as surgery on the wrong body part, proper surgery on wrong patient, and wrong surgery, is so severe that States are likely to rely on other plan authorities and coverage options to deny payment for these events. Three of the States with HCAC-related SPA have implemented policies that expand nonpayment policies to settings other than the inpatient hospital setting required by Medicare. Massachusetts, Minnesota, and New Jersey apply their respective policies to hospitals and physicians. Massachusetts also has expanded its policy to ambulatory surgical centers.

CMSO identified eight States (Alabama, Colorado, Maine, Maryland, Missouri, Oklahoma, Pennsylvania, and Washington) that have implemented Medicaid HCAC-related nonpayment policies that have not submitted State plan amendments. These States relied on existing Federal statutory authority, State plan language, and State legislation to implement nonpayment policies. Just as with the States that did submit SPA, the policies vary from State to State.

Of the “non-SPA” States, Colorado, Missouri, Washington, Alabama, and Oklahoma have adopted Medicare’s current HAC list as their corresponding lists of events. Oklahoma has also identified the three Medicare NCD for nonpayment under its program. Missouri and Washington have identified the three Medicare NCD, as well as the remaining 25 NQF serious reportable events, for nonpayment under their respective policies. Maine elected, as did Massachusetts mentioned earlier, to adopt the NQF serious reportable events as identifiable for nonpayment, but did not adopt any of the Medicare HAC. Pennsylvania identified its own list of conditions combined from evidence-based sources, but not fully tied to Medicare’s current list of HAC or the NQF serious reportable events.

The non-SPA States, too, have employed varied terminology for their nonpayment policies. Again, these policies often cover the same types of conditions with the same medical definitions and research sources. Note that the variances in terminology should not be underestimated or disregarded. The unique position of States selecting conditions and the various scientific indicators related to condition preventability, quality indicators, and system nuances present a difficult situation for creating consistency across programs. Maine and Missouri have expanded their nonpayment policies to ambulatory surgical centers. Oklahoma applies its HAC policy only to inpatient hospitals, but has applied its NCD list to all providers. Pennsylvania has expanded its list of “Preventable Serious Adverse Events” to all health care providers and facilities within the State. It is important to note that States use different general terminology for HCAC-related nonpayment policies even though many of the conditions identified overlap, are from the same sources, and do not generally vary in medical definition from one list to the other. For example, Kansas includes air embolisms on its list of “Hospital Acquired Conditions”; New York includes the same condition as a “Serious Adverse Event”; and New Jersey includes it on a list of “Medical Errors.”

SECTION 4 DISCUSSION AND CONCLUSION

4.1 The Role of Recent Federal Initiatives and the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) for State Reporting and Nonpayment of Health Care-Associated Conditions

4.1.1 The Recovery Act, Health Care-Associated Infections, and State Expansion of the National Healthcare Safety Network

The HAI Recovery Act initiative carried out by the Centers for Disease Control and Prevention (CDC) has prompted a large expansion of State-level reporting of Health Care–Associated Infections (HAIs). Although some States were already collecting data on at least one HAI through 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 Health and Human Services (HHS) agencies and other stakeholders, including clinicians, payers, and consumers to ultimately prevent infections and reduce deaths. The 22 States that already use or have agreed to begin using the National Healthcare Safety Network (NHSN) for surveillance of HAIs are likely to increase in number as these HAI prevention programs are implemented and gain traction among key State leaders and policymakers.

Mandatory HAI reporting on the Federal level will begin in 2011 for two HAI measures: (1) central line–associated blood stream infection (CLABSI) and surgical site infections (SSI). Per the final Inpatient Prospective Payment System (IPPS) rule published August 16, 2010, CLABSI reporting will begin in 2011, and SSI reporting will begin in 2012. Both measure sets will be used for the fiscal year (FY) 2013 payment determination (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.

4.1.2 Patient Safety Organizations (PSOs) and the Patient Safety Act

The Patient Safety Act of 2005 named 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, 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 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.

4.1.3 The Patient Protection and Affordable Care Act of 2010

Improving the quality and efficiency of health care is one of the provisions of The Patient Protection and Affordable Care Act (Affordable Care Act, 2010) signed into law in March 2010 by President Obama. 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. 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, Maryland, and critical access), 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 will be submitted no later than January 1, 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.

4.2 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 3 out of 5 States (32) track at least one HAC; 22 of those States track at least one infection from the Medicare list of HACs through 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 1 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.

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 does call for stronger patient safety protections in the 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.

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APPENDIX A
MEDICARE LIST OF HOSPITAL-ACQUIRED CONDITIONS

The CMS list of HACs is divided into 10 categories. Effective October 1, 2008, CMS no longer pays a higher reimbursement for hospitalizations complicated by these categories of conditions that were not 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*
 - A. Fracture
 - B. Dislocation
 - C. Intracranial injury
 - D. Crushing injury
 - E. Burn
 - F. Electric shock
6. Manifestations of poor glycemic control*
 - A. Hypoglycemic coma
 - B. Diabetic ketoacidosis
 - C. Nonketotic hyperosmolar coma
 - D. Secondary diabetes with ketoacidosis
 - E. Secondary diabetes with hyperosmolarity
7. Catheter-associated urinary tract infection
8. Vascular catheter-associated infection
9. Deep vein thrombosis/pulmonary embolism associated with
 - A. Total knee replacement
 - B. Hip replacement
10. Surgical site infection
 - A. Mediastinitis after coronary artery bypass graft
 - B. Associated with certain orthopedic procedures involving the
 - a. Spine
 - b. Neck
 - c. Shoulder
 - d. Elbow
 - C. Associated with certain bariatric surgical procedures for obesity
 - a. Laparoscopic gastric bypass
 - b. Gastroenterostomy
 - c. 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).

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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