ELIMINATING
Healthcare-Associated Infections

State Policy Options

CDC
Centers for Disease Control and Prevention

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EXECUTIVE SUMMARY

The Case for Elimination

As a significant cause of death, healthcare-associated infections (HAI) are a critical challenge to public health in the United States. HAI are infections that patients acquire when receiving healthcare treatment (www.cdc.gov/HAI). At any given time, about 1 in 20 patients have an infection while receiving healthcare treatment in U.S. hospitals. HAI in hospitals alone result in up to $33 billion in excess medical costs every year. Despite these staggering statistics, these infections are preventable and comprehensive programs are needed to make progress toward the goal of eliminating HAI.

Several federal initiatives are now underway to advance HAI prevention, making this an opportune time for states to initiate or enhance their HAI programs, including efforts to ensure that valid data are reported. State health agencies have a central role to play in HAI elimination because they are responsible for protection of patients across the healthcare system and serve as a bridge between healthcare and the community. The purpose of this toolkit is to provide guidance to senior policy makers on various promising ways to use legal and policy interventions as tools to implement comprehensive HAI prevention programs. The interventions suggested in this toolkit may be effectuated jointly through law, in the form of legislation, regulation, and rulemaking, and public policy, which may not be legally enforceable, but intends the same goals. For example, regulatory and oversight tools are significant levers for effective prevention of HAI that can be uniquely tailored in states. Further examples of existing state laws and policies are discussed below.

Capacity for HAI Program Implementation

State health agencies planning to use policy interventions should first consider whether adequate authority has been granted by the state legislature to create a new program or draft new regulations and rules that may be needed in order to engage in HAI prevention activities. When deciding whether to adopt any of the provisions in this toolkit, careful consideration should be given to whether a provision should appear in statute or regulation. State legal counsel should be consulted before drafting legislation to ensure compliance with existing statutes and authorities. Essential provisions in HAI statutes should define an agency's power to:

- Implement an HAI program.
- Enforce the HAI law.
- Ensure the program's sustainability.
- Protect the confidentiality of data.
- Regulate as necessary.

Prevention Implementation and Sustainability

There are many legal and policy tools available to catalyze HAI prevention. Adherence to evidence based practices can be promoted through:

- Public reporting of data to provide feedback on how to best target prevention efforts.
- Advisory councils to provide guidance.
- Appropriate accreditation, training and licensure to promote adherence to best practices.
- Financial incentives to sustain programs.
- Oversight capacity to ensure patient safety.

HAI reporting provisions represent the most extensive component within existing state HAI statutes and have largely been driven by consumer demand for transparency and accountability on HAI. In 2004, only three states had public reporting mandates. That number has grown to 28 states in 2011.

States can link their reporting requirements to their other HAI regulations to create a comprehensive strategy for addressing HAI. States should engage key stakeholders, including healthcare facilities and advisory councils, when drafting and implementing new laws or policies. It is recommended that funding of state programs be addressed in legislation. Whenever possible, states are encouraged to choose incentives to encourage facility compliance over disincentives for discouraging non-compliance to help promote a culture of safety and proactive HAI prevention approaches.

Conclusion

Despite current progress towards the elimination of HAI, there is much work to be done to sustain state HAI prevention programs. Policy interventions can help accelerate HAI prevention through implementation of a public health model that promotes adherence to evidence-based practices and uses valid data to respond to emerging threats and focus prevention efforts. For HAI elimination to succeed each state will need to implement or expand appropriate state policies. For those states pursuing policy change, ensuring that appropriate state statutory, regulatory, and administrative tools are in place provides a foundation to accelerate HAI elimination for now and for generations to come.

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I. INTRODUCTION: The Case for Elimination

As a significant cause of death, healthcare-associated infections (HAI) are a critical challenge to public health in the United States. HAI are infections that patients acquire during the course of receiving healthcare treatment (www.cdc.gov/HAI). These infections can be devastating and even deadly, and are preventable. At any given time, about 1 in 20 patients have an infection while receiving healthcare treatment in U.S. hospitals. HAI in hospitals alone result in up to $33 billion in excess medical costs every year, billions which could be saved through implementation of comprehensive HAI prevention programs. HAI are associated with substantially increased excess healthcare costs. For example, a single central-line associated bloodstream infection (CLABSI) could result in an estimated $16,550 in excess medical costs.

In addition, more healthcare is being delivered in non-hospital settings, such as ambulatory surgical centers, dialysis clinics, private doctors' offices, and long-term care facilities, where additional patients are affected with HAI. The burden of HAI outside acute care settings is largely unknown and based on few estimates. For example, nationally there are approximately 1.7 million long-term care beds in which 1.6-3.8 million infections are estimated to occur per year. Based on these estimates, infections in long-term care residents may account for between 23,100 to 70,000 deaths per year in the United States. Dialysis clinics are a major contributor to the burden of CLABSIs, with approximately 37,000 CLABSIs estimated a year among hemodialysis patients. Recent inspections conducted by the Centers for Medicare and Medicaid Services (CMS) identified infection control lapses in two-thirds of ambulatory surgical centers (ASCs). Each of these settings contributes to different aspects of the HAI burden. Lack of adherence to fundamental infection control practices, including the reuse of syringes and the reuse of single-dose medication vials, has resulted in numerous outbreaks of HAI in ASCs.

A Parent's Story

Josh Nahum, age 27, passed away in 2006 as a result of a healthcare associated infection. His infection was from a type of bacteria called Gram-negative. Gram-negative infections loom heavy as one of the greatest challenges of our time because this type of bacteria cannot be treated by most or all antibiotics. Josh's infection struck him while he was recuperating from an injury. Just as he was progressing, his infection was discovered within his cerebral spinal fluid. From there, it continued to develop rapidly, causing so much pressure around his brain that it actually pushed part of it into his spinal column making him a permanent quadriplegic. Josh died 2 weeks later. This is just one example of the tragic consequences of an HAI that could have been prevented.

The purpose of this toolkit is to provide guidance to senior policy makers on various promising ways to use legal and policy interventions as tools in implementing a comprehensive HAI prevention program. While some states may choose not to pursue legal interventions such as legislation, regulation, and rule making, these approaches are among the options available to states to address HAI. Building relationships with and engaging key stakeholders that will be involved in or impacted by the new program is also a critical step that will benefit the development, implementation, and sustainability of the program.

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Moving toward Elimination

Despite these staggering statistics on the incidence of HAI, we now know that these infections are preventable. Comprehensive programs are needed to make progress toward the goal of eliminating HAI. In the past, HAI were considered an unfortunate consequence of healthcare. In recent years there has been a shift in this attitude and recognition that HAI are an unacceptable problem that can be prevented and even eliminated.[1] Recent local and regional initiatives have shown dramatic reductions of approximately 70% in some types of HAI in hospitals, and these reductions have been sustained.

Elimination of HAI requires a public health model of constant action and vigilance to promote adherence to evidence-based practices; alignment of incentives and reinvestment in successful strategies; filling knowledge gaps to respond to known and emerging threats through research; and collecting data to target prevention efforts and to measure progress. These efforts must be underpinned by sufficient financial investments and resources (Figure 1).[2]

Figure 1. Framework for the elimination of healthcare-associated infections.

States Have a Critical Role to Play in HAI Prevention

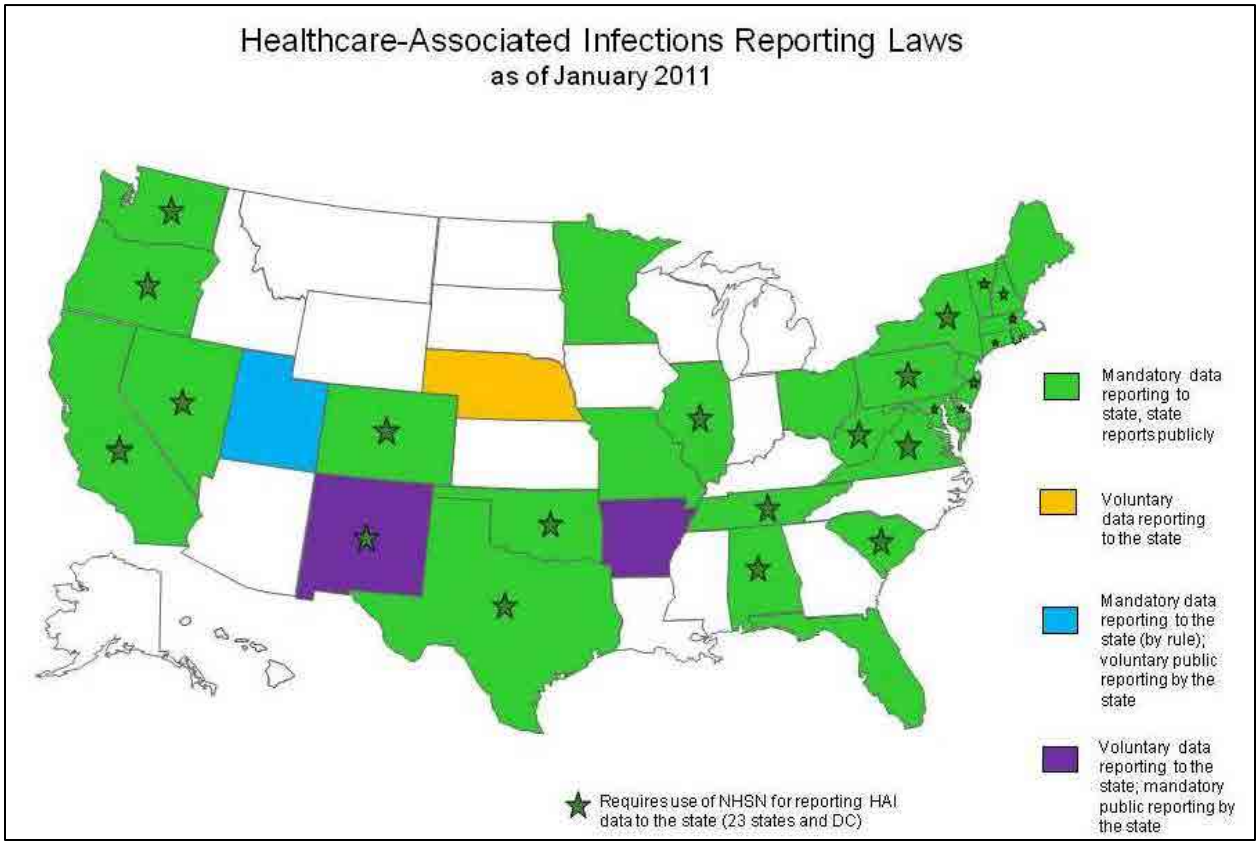
State[i] health agencies have a central role to play in HAI elimination because they are responsible for protection of patients across the healthcare system and serve as a bridge between healthcare and the community. States are uniquely situated to forge collaborations among the various entities that play a role in HAI reporting and prevention, and have authority to regulate and inspect facilities, collect and validate data on infections, and implement improvement programs while also maintaining the requisite level of privacy and confidentiality to protect patients' rights. To combat HAI, some of the tools health

[i] Note that while the term "state" is used throughout this document, the language and examples provided may be applicable and useful to tribal, local and territorial health departments as well.

officials may consider include legal and policy interventions. These interventions, done well, have the ability to promote the principles of safety, accountability, and transparency that are central to the battle against HAI.

The Role of Policy in HAI Reporting and Prevention

Consideration of national drivers for HAI prevention is important when evaluating states' needs for HAI legislation. Several federal initiatives are now underway to advance HAI prevention, making this an opportune time for states to develop or enhance their HAI programs. In the last 10 years, much has changed in the political, scientific, and social climate surrounding HAI. There has been a rise in the profile of consumer advocates and public outrage over the extent of HAI in the U.S. as well as a growing societal expectation in many parts of the country for HAI to be publicly reported. As of January 2011, 32 states and the District of Columbia have passed laws pertaining to HAI prevention and reporting. Many states also have HAI-related regulations, indicative of the growing role of states in addressing this issue. A series of high-profile outbreaks following breaches in infection control procedures, particularly in out-patient settings, has led to regulatory and other policy actions in states.



In 2009, the US Department of Health and Human Services (HHS) developed the *Action Plan to Prevent Healthcare-Associated Infections*, to assess national progress in reducing HAI rates with an initial focus on acute care settings ("Tier I"). Tier I of the *HHS Action Plan* includes nine initial goal areas: central line-associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, Methicillin-resistant *Staphylococcus aureus (*MRSA) and *Clostridium difficile* (2 goals each), central line

insertion practices, and surgical care measures. The priorities outlined in this document have formed the basis for prioritizing HAI prevention and elimination efforts at the federal, state and local levels. HHS will soon be releasing Tier II of the HHS Action plan, focusing on HAI prevention in certain non-hospital settings.

Sustained support for HAI programs is essential for legislative or policy measures to succeed. American Recovery and Reinvestment Act of 2009 (ARRA, or "stimulus") funding helped to ensure that some basic elements of HAI program infrastructure are now present in all state health agencies. Recovery Act investments enables states to engage in various activities such as developing HAI Action Plans; developing or enhancing infrastructure for tracking infections, measuring impact, and promoting HAI prevention; and developing HAI Advisory Councils, for those states that did not previously have one. This was the first dedicated funding ever provided to states for these purposes. The one-time ARRA funding ends in FY 2011 and, in several states, this infrastructure will be disassembled once the funds have been expended.

The Patient Protection and Affordable Care Act of 2010 (Affordable Care Act, or "health reform") placed further emphasis on HAI prevention through the CMS Hospital Inpatient Quality Reporting Program, creating a *de facto* national mandate for public reporting of HAI (see further discussion below, "Reporting of Healthcare-Associated Infections," page 12). In order to receive their full payment update from CMS, hospitals will be required to report on select infections via CDC's National Healthcare Safety Network (NHSN), and the information will be publicly available on CMS' Hospital Compare website. In January 2011, acute care hospitals began reporting CLABSIs in intensive care units (ICUs) and neonatal intensive care units (NICUs). Requirements to report certain surgical site infections (SSI) will begin in January of 2012, and additional categories of HAI will follow. This is a significant driver for hospitals with upwards of 95% of acute care facilities participating in this program. Despite federal drivers for public reporting of HAI data, it must be stressed that state policies serve as valuable tools for HAI prevention activities due to their role in creating a comprehensive HAI prevention program that is not accomplished by these federal initiatives alone.

In addition, federal pay for performance and value based purchasing strategies will be implemented in 2013 through the Affordable Care Act, and will also have implications for state considerations for incentive systems. New "meaningful use" requirements for collection and use of health data also enacted in the health reform law will continue to drive reporting and public health use of data to inform decision-making.

Notwithstanding current initiatives for HAI reporting and prevention, there remains a critical need to improve adherence of clinicians and healthcare facilities to infection control and HAI prevention guidelines through partnerships, education, implementation, and investments. Unfortunately, current practice has not caught up with the science regarding HAI elimination. Policy interventions can bring a focus on preventing patient harm and challenge the health system to no longer accept the unacceptable. For example, payment policies can provide incentives to catalyze the development of systems of care that are prevention oriented. Vigilance to change the *status quo* will require institutional change and policy interventions can play an important role in achieving such change. High standards of

accountability also will be needed to make sustained elimination a reality. Data collected to target HAI prevention efforts and measure progress provides accountability and transparency. Mandatory reporting policies through standards based systems, such as NHSN, provide more comprehensive data for decision-making, and are thus the preferred approach for those states pursuing policy interventions. These are all key roles for states, and should be considered in the development of state HAI programs.

Regulatory and oversight tools at the state level, such as powers granted to a health department to enforce regulations or require reporting of HAI, are significant levers for effective prevention of HAI that can be uniquely tailored in states and are useful in both hospital and non-hospital settings. States are rapidly implementing or expanding effective policies and regulations. Examples of existing legal and policy strategies include:

- Providing incentives for HAI prevention.
- Increasing survey/certification activities across the spectrum of care.
- Implementing licensure and training requirements.
- Increasing adherence of healthcare facilities and providers to infection control recommendations.
- Implementing or expanding public reporting.
- Ensuring appropriate regulatory oversight.

While this document is intended to provide impetus for thoughtful consideration of HAI-related strategies and to suggest possible approaches for addressing those issues, the suggested array of provisions must be considered within the policy and legal frameworks of the jurisdiction considering adopting them.

Development and Use of this Toolkit

This toolkit was developed jointly by the Association of State and Territorial Health Officials (ASTHO) and CDC. Following a review of existing state HAI laws and programs, an expert working group was convened comprised of state health agency staff, legislative liaisons, legal counsel, infection preventionists, epidemiologists, and consumer advocates who provided invaluable insights and assistance during the research, deliberations and drafting of document.

Disclaimer: *Information contained in this document does not constitute legal advice and does not represent the legal views of ASTHO, CDC, or HHS. Use of any provision herein should be considered only in conjunction with advice from legal counsel. Provisions may need to be modified, supplemented, or replaced to ensure appropriate citation to, or compliance with relevant laws, or to otherwise address the needs or requirements of a specific jurisdiction.*

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II. CAPACITY FOR HAI PROGRAM IMPLEMENTATION

State health agencies planning to use policy interventions should first consider whether adequate authority has been granted by the state legislature to create a new program or draft new regulations and rules that may be needed in order to engage in HAI prevention activities. The following section describes areas in which state health agencies may need to pursue specific authorities. Examples of states with successful statutory grants of authority are Missouri, New Hampshire, New Jersey, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Vermont, and Washington referenced in Appendix I.

Statutes vs. Regulations

When deciding whether to adopt any of the provisions in this toolkit into law, careful consideration should be given to whether a provision should appear in statute or regulation. States are encouraged to adopt broad or general statutes that confer discretion to the regulatory process, which can be more expeditiously exercised to make changes or updates. Other factors include the timeframe in which the regulation may be promulgated by the authorized agency or the statute enacted by the legislature; how often changes might need to be made to the law; whether the subject matter of the legal provision is technical, and regular updates are likely according to advances in technology or practice; and whether statutory authority exists to promulgate a regulation. Regulations must be authorized by statute (i.e., there can be a statute without a regulation, but not a regulation without an authorizing statute). In some cases, appropriate authorizing statutes may already be in place.

In addition to authorizing language to create regulations, there are some issues that in many states must be addressed in statute. These include confidentiality provisions and privilege protections to protect data reported to states, authority to regulate healthcare settings, and authority to enforce penalties when established standards are not met. Data sharing authority may also be addressed in statute. State legal counsel should be consulted before drafting legislation to ensure compliance with existing statutes and authorities.

Many state governments are currently supporting robust HAI prevention programs and require HAI-specific legislation for health agencies to effectively inspect, report, and control emergent HAI regardless of where care is delivered. Effective HAI legislation delegates authority to the state health agency, commissioner of health, other regulatory agencies, HAI advisory councils, and other government officials to structure an evidence-based HAI program. State health agency authority is important to promote HAI prevention and does not preclude federal incentive programs for HAI reporting.

Essential provisions in HAI statutes should define an agency's power to:

- Implement an HAI program.
- Enforce the HAI law.
- Ensure the program's sustainability.
- Protect the confidentiality of data.
- Regulate as necessary.

Each of these basic authorities is discussed below.

Creating and Implementing HAI Programs

State HAI laws should grant authority for regulatory oversight to either the state health agency or commissioner of health. A state health agency's power to oversee and regulate HAI prevention and control activities is generally granted or delegated by the state legislature. The term "regulatory oversight" refers to the activities a state health agency or other administrative agency conduct to implement or apply the provisions of an enacted HAI statute. "Covered" entities defined in statute such as hospitals and other health care providers are the entities for which the state agency has regulatory oversight.

Granting of broad authority is preferable to promote HAI prevention. Highly prescriptive statutes that require yearly amendments and hearings do not allow a state health agency the flexibility to quickly respond to emergent HAI, new technologies, and changing facility needs through agency rules and regulations. A state legislature will ideally delegate authority to a health agency to regulate the HAI-related activities of any health facility pursuant to the state's administrative procedures act (APA). State APAs define the procedures for agency rulemaking and adjudication, but typically do not address substantive or programmatic issues.

A state with separate statutes defining health and regulatory authorities will need to either cross-reference each law or amend both laws simultaneously to coordinate HAI programs and regulations. While these requirements vary greatly by state, they are often needed to coordinate regulatory or licensing powers with health agency functions, communicable disease laws or medical error laws with HAI laws, sentinel event reporting with HAI reporting, and definitions of civil and criminal penalties in the healthcare facility setting.

Enforcing the HAI Law

HAI law should motivate and guide facilities to make essential improvements, as necessary, in a timely manner and respond to emergent HAI. By granting authority to a state health agency to enforce its HAI mandate, a state legislature can ensure that facilities will meet the requirements and take corrective action if needed, they will merit licensure, and that providers will undergo appropriate training and certification in HAI prevention and control. The scopes of authorities that will ideally accompany any HAI statutory mandate are presented below.

Table 1: Scopes Of Authorities In State HAI Legislation.

Statutory Authority Granted To	Reason For Enforcement	Type Of Enforcement Authorized
Health Agency	Facility insufficiently or inaccurately reports HAI data or reports unsatisfactory HAI rates	- Inspection of facility records or HAI-related data - Create a plan for facilities to undertake corrective action
Health Agency or State Licensing Authority	Facility fails to report or fails to improve unsatisfactory HAI rates	- Facility licensure sanctions for non-reporting or poor healthcare quality or patient safety
Health Agency, Provider Licensure or Accreditation Authority	Facility reports unsatisfactory HAI rates specific to individual providers	- Requirements for training in HAI best practices and certification in infection control - Provider accreditation sanctions for poor healthcare quality or patient safety

Ensuring a Program's Sustainability

Another key element of a state statute is to provide for HAI program sustainability. To create an effective and lasting HAI program, a statute could authorize a health agency to:

- Provide financial incentives and disincentives and collaborate with insurance or licensing authorities to do the same.
- Receive funding dedicated specifically to HAI control and prevention.
- Collect licensing fees to support the HAI program.
- Collect fines for statutory violations, set on a sliding scale according to the degree of risk and length of violation that are returned to fund the HAI program itself.

Protecting Patient Data

State statutes must protect patient data for an HAI program to be legal, trustworthy, and politically feasible. Enacting patient confidentiality provisions in addition to available privacy protections increases public confidence in HAI data collection activities. Individual privacy is protected both constitutionally and statutorily at the federal level, although state constitutions and state statutes may enhance these protections to varying degrees. It is essential to understand state privacy law through advice of counsel before drafting further patient protection provisions that may affect the use of patient data.

Many states have included confidentiality and privilege protection clauses in their HAI legislation that address individuals, institutions, data, and data use allowance. An HAI statute can protect patient data from disclosure in four ways:

- The statute can reference existing privacy laws. The U.S. Constitution, Health Insurance Portability and Accountability Act (HIPAA), and federal privacy laws, as well as state constitutions and privacy laws, protect individuals from government intrusion into their personal affairs. These protections have been interpreted to include patient data.
- The statute can strengthen patient (and sometimes healthcare worker or facility) protection by protecting identifiers from public disclosure or data reports.
- An HAI statute can provide for the confidentiality of data, except where state law must allow regulatory or licensing authorities to be able to inspect records and determine the extent of violations.
- An HAI statute can include a privilege provision that protects patient data from discovery or use in legal or administrative proceedings against a facility or provider. Some states choose to grant additional protections for facilities and providers from litigation, with exceptions for regulatory, licensing, or accreditation authorities to inspect records and determine the extent of violations.

Balancing Privacy with Protecting the Public's Health

Protections for individuals or entities providing healthcare may be challenging at times when patient safety is at risk and known to health officials. In states where extreme unsafe practices have been discovered by state regulatory entities, the need for criminal prosecution and notification of medical boards of illegal and unsafe practices may be necessary to prevent further harm. States must strike a balance between the need to encourage facilities and healthcare providers to seek help from state health agency prevention staff for HAI-related problems without fear of reprisal, while ensuring that patients are safe from egregious practices once they are discovered. In Nevada, health authorities are authorized to conduct investigations concerning infectious diseases, petition the court for a subpoena to compel the production of information relevant to those investigations, and issue cease and desist orders against a provider of health care or medical facility subject to such an investigation. In addition, if the Health Division suspends the license of a medical facility, they may take control of certain medical records of the facility.

Public health agencies must also balance the need for regulatory agencies to act on breaches in infection control, while preserving healthcare facilities' ability and willingness to ask for help when needed. Healthcare facilities and practitioners may be reluctant to accurately report infection data due to the fear of harm to individual reputation, civil litigation or administrative actions. Some states resist punitive administrative actions by restricting access to HAI program data for both civil litigation and administrative actions.

III. PREVENTION IMPLEMENTATION AND SUSTAINABILITY

Authority provided through statute enables state health agencies to engage in HAI prevention activities. Once legal authority exists, there are many policy tools available to influence and catalyze HAI prevention. This portion of the toolkit addresses specific options for implementation and sustainability of HAI prevention programs. Adherence to evidence based practices can be promoted through these tools:

- Public reporting of data to provide feedback on how to best target prevention efforts.
- Advisory councils to provide guidance.
- Appropriate accreditation, training and licensure to promote adherence to best practices.
- Financial incentives to sustain programs.
- Oversight capacity to ensure patient safety.

Reporting of Healthcare-Associated Infections: Patient Safety, Transparency and Accountability

HAI reporting provisions represent the most extensive component within existing state HAI statutes and have largely been driven by consumer demand for transparency and accountability on HAI in healthcare facilities. In 2004, only three states had public reporting mandates. That number has grown to 28 states as of the beginning of 2011.

Within states, HAI are reported for multiple uses including facility safety and quality improvement activities, public health and epidemiologic use, and public reporting. Public reporting is an important tool in providing data for HAI prevention activities, as well as accountability to consumers to reduce HAI occurrences. Previous guidance on developing HAI reporting systems exist, including guidance from CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC). The recommendations included here are consistent with this guidance.

There is a set of common elements found in many of the existing examples of public reporting legislation including:

- Mandatory reporting and types of reporting systems.
- Reporting outside of hospitals.
- Reporting measures (designating what data are reported and what units should report).
- Data validation.
- Formats and frequency of public reporting.
- Reporting implementation timeline.
- Pathogen specific legislation.

In many states, some of the implementation details (e.g., what data should be reported, what units should report the data) are implemented through a state advisory council and regulations (see "Advisory Councils" section for more information) and are not detailed in the actual legislation. Many states have

found this form of implementation useful to allow for maximum input from experts and stakeholders into these decisions and flexibility to adapt to state needs.

Reporting of HAI Data and Types of Reporting Systems

Mandatory reporting has driven HAI prevention in many states. Currently 29 states and D.C. require reporting of HAI to the state health agency or other state-level entity, such as a hospital association or quality improvement organization. An additional three states have created reporting procedures through statute or rule.[ii]

Mandatory reporting policies have been demonstrated to produce comprehensive data for use in tracking HAI rates at the state and local level, including data on a broad range of facilities and infections. Ensuring sufficient data sets allow for better data validation and statistical analysis, thus producing more actionable information from the program. Additionally, when data are validated, mandatory reporting provides confidence in a more accurate picture of HAI rates across all facilities. As discussed in subsequent sections of this toolkit, states can link their reporting requirements to their other HAI regulations to create a comprehensive policy strategy for addressing HAI. Though there are many benefits to mandatory reporting, it requires additional resources to support prevention efforts, analyze and validate data, as well as achieve and maintain buy-in from healthcare facilities and other stakeholders. States should be sure to engage key stakeholders, including healthcare facilities, when drafting and implementing new mandatory policies.

Alternatively, states with voluntary reporting note that they are able to acquire useful data while maintaining strong relationships with healthcare facilities, who may be concerned about the implications of mandatory policies. Some states (IA, MI) with voluntary reporting have had demonstrated success using this mechanism . Other states have reported interest from healthcare facilities in partnering on HAI prevention; establishing voluntary reporting maybe particularly helpful in these instances, if enacting new legislation to require reporting is not fiscally or politically feasible. However, challenges exist with voluntary reporting systems. In some states with voluntary reporting systems, health agencies struggle to implement HAI prevention programs because they lack the authority, capacity, or funding to require facilities to report

National Healthcare Safety Network (NHSN)

CDC established NHSN, a secure, web-based surveillance system that facilitates HAI reporting from healthcare facilities in addition to HAI prevention activities. Enrollment is open to a range of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. The majority of states with mandated HAI reporting use NHSN, and it is the recommended system for states considering mandatory reporting. NHSN participation has grown to include more than 4,100 healthcare facilities across the U.S. as of January 2011. (www.cdc.gov/nhsn)

[ii] Additional states may collect data from healthcare facilities on HAI on a voluntary basis through policies that do not require legislation; however such programs were not included in this phase of analysis.

HAI, monitor statewide HAI trends, or even identify breaches in infection control practices. For example, most states without mandatory reporting laws had fewer hospitals participating in HAI reporting and prevention collaboratives compared to states with mandates. There is concern that under voluntary reporting policies, those facilities with high HAI rates may choose not to report and that outpatient settings, where many recent large-scale infection control breaches have occurred, may have no incentive to participate, thus painting an inaccurate picture of HAI statewide.

The vast majority of states (28 of 29) with mandatory HAI reporting to the state also have a mandate for the state to report their HAI data publicly. CDC supports public reporting of validated data and provides a system for reporting through NHSN. The following sections describe implementation, formats, and frequency of public reports in detail.

As an initial step, states may want to choose certain infections or procedures for public reporting, while maintaining more comprehensive mandatory reporting to the state health agency. For example, Utah mandates reporting of certain HAI outcomes to the state health agency, while only reporting process measures (e.g., compliance with infection control procedures) publicly. California legislation identified several measures for initial reporting based on measures identified as appropriate for mandatory public reporting by HICPAC and indicated that an "advisory committee shall make recommendations for phasing in the implementation and public reporting of additional process measures and outcome measures … and … shall consider the measures recommended by the CDC"(see Appendix I).

Overall, most states with public reporting legislation have chosen to use NHSN as their data collection system but a few states have other state-specific HAI reporting systems in use. Importantly, NHSN has standard definitions, standard protocols for data collection, data validation checks, and data analysis tools for HAI prevention. It thus provides actionable data for HAI prevention, national benchmarks against which to measure progress, and provides facilities with risk-adjusted data that can be used for assessing facilities' progress in HAI prevention and internal quality improvement activities such as identifying problem areas and targeting units that need assistance. Use of the NHSN Patient Safety Component is mandated in 23 states and DC[iii]. With the implementation of CMS' Hospital Inpatient Quality Reporting Program, NHSN will be used in approximately 5,000 hospitals in the U.S. to report data, which will be available to state health agencies. States that intend to use NHSN for reporting should consider specifying NHSN as the HAI reporting system within statute or regulation to facilitate implementation. California provides a good example of statutory language on mandatory reporting using NHSN (see Appendix I).

[iii] AL, CA, CO, CT, DC, DE, IL, MA, MD, NH, NJ, NM, NV, NY, OK, OR, PA, SC, TN, TX, VA, VT, WA, WV

CDC has recently made changes to NHSN, enabling CDC to provide state health agencies, at their request, access to HAI data for surveillance and prevention purposes. The updated data access provisions allow hospitals to work closely with their respective health agencies and to comply with new Medicare reporting requirements. This will enable use of the public health model for HAI prevention in which CDC, state health agencies, and healthcare facilities work together to eliminate HAI. States requesting access to data in NHSN beyond the infections covered in their state mandate can do so by a data use agreement with CDC. States should investigate whether additional authority is needed from the state legislature to enter into such an agreement, and, if needed, pursue it in the initial drafting of legislation. This type of agreement does not replace the need for HAI mandates for those states that wish to have more comprehensive data available to them, as the CMS policy will only collect data on certain conditions from hospitals; should states wish to access data on conditions other than CLASBI and SSI, or from other types of facilities, additional reporting will be needed.

State Approaches Outside Hospitals

It is important to recognize the important public health role that health agencies play in preventing HAI outside of acute care. To ensure patient safety, appropriate authorities for health agencies are needed. For example, New Jersey statute allows the commissioner of health, through regulation, to "…expand the health care facility-associated infection reporting requirements in this act to other types of health care facilities (CHAPTER 196 C.26:2H-12.44)." Other states provide examples of provisions for reporting from other facilities such as long term care facilities, ambulatory surgical centers (e.g., CO, NV), nursing facilities, home nursing care providers and licensed health care providers (e.g., RI), birthing and obstetric centers (e.g., DE), centers or group homes for the developmentally disabled (e.g., NE), and correctional facilities (e.g., DE). As more complex procedures are performed outside of acute care, states should consider reporting requirements based on procedure performed rather than reporting from specific locations (See Appendix II for examples of statutory language).

Reporting HAI Outside Hospital Settings

While most states focus on reporting from acute care hospitals, healthcare is increasingly provided in facilities other than hospitals. For example, long term care settings account for a significant portion of *Clostridium difficile* infections (CDI) and catheter-associated urinary tract infections (CAUTI), while dialysis clinics are a major contributor to the burden of CLABSIs. State health agencies have a vital role in HAI prevention as patients move throughout the healthcare system.

Transmission of infections across healthcare settings (e.g., from hospitals to long-term care facilities) is a major factor of concern in HAI prevention. Reporting requirements can ensure valid data on infections that appear once patients have left the hospital are captured to aid in reducing spread of infections to other facilities and patients. To this end, some states not only collect information through surveillance by infection preventionists, but require physician reporting of infections if diagnosed on medical follow-up. For example, Colorado and Delaware statutes require physicians who perform clinical procedures to report to the health facility where the procedure was performed if an HAI is diagnosed on follow-up.

Pennsylvania law requires healthcare facilities to notify a patient or their legal representative when a reportable HAI has occurred.

Reporting Measures and Units

Specific requirements for reporting measures will vary by state, but understanding federal reporting requirements can serve as a starting place for developing reporting requirements. As mentioned earlier, under CMS's Hospital Inpatient Quality Reporting Program, selected CLABSIs and SSIs will be reported to CMS by acute care hospitals starting in January 2011 and January 2012, respectively, with other measures in the *HHS Action Plan* to follow (see Appendix II). Advisory councils can recommend additional measures to address changing federal reporting requirements (e.g., implementation of Tier II of the *HHS Action Plan*) and state specific needs.

Process measures are important for promoting HAI prevention. There are many examples of process measures focused on patient safety and quality that are included in state statute. The process measures that HICPAC recommended in 2005 include central line insertion practices (targeting ICUs), surgical antimicrobial prophylaxis and influenza vaccination coverage rates for long-term care facilities. There are additional process measure reporting requirements in state statutes including those related to ventilator-associated pneumonia (IL); adherence to recommended healthcare practices such as hand hygiene (ME, MN, IL); and staffing, including nursing hours per patient day, average daily hours worked for clinical service areas, yearly reports on vacancy, or turnover rates for licensed nurses (IL). In review of legislation, we found only Illinois requires reporting on nurse staffing; however, this may be an important process measure for HAI prevention and consideration of reporting on staffing for infection preventionists may be of value as well.

Reporting of infections from different locations within facilities or from locations where follow-up care may occur is an important consideration. While there is variation, most states with mandatory reporting begin reporting with CLABSIs in hospital ICUs. Because CMS requires hospitals to report CLABSIs, states planning to enact mandatory reporting should consider additional measures beyond ICU-related CLABSIs. There is evidence to suggest that high CLABSI rates outside the ICU setting are useful to report and track given the large number of patients that require a central line outside of an ICU[3,4,5]. States should consider initiating reporting for one (e.g., CLABSIs) or two (e.g., CLABSIs and SSIs) types of infections within specific high risk units and subsequently phasing in reporting to additional relevant hospital units and types of healthcare facilities and for additional infection types over time.

Data Validation

Having valid data and a valid system for collecting it is critical to a successful HAI program. The use of data collected using standard definitions and protocols has been shown to more accurately reflect HAI rates than proxy data such as administrative data[6,7]. It is important for states to participate in validation efforts for prevention and reporting purposes. For example, in the *First State-Specific HAI Summary Data Report* (2010) produced by CDC, states conducting data validation efforts reported more infections than those without data validation efforts, suggesting that without valid data, many infections may go undetected.

States such as New York include a statement of the need for validation in statute and have funded and implemented requirements at the programmatic level. New York, South Carolina, Tennessee, Connecticut, and Maryland have all implemented exemplary validation processes through the state health agency. Many states are using ARRA funds to work with CDC on further data validation, such as through chart reviews. Some elements of good data validation processes include requirements for hospitals to follow standardized infection data collection and reporting procedures; requirements for health agencies to develop and implement an audit process to assure the accuracy of the self-reported HAI data and to assure that public reporting fairly reflects what actually is occurring in each hospital; and time for completion of data validation prior to public reporting of data to ensure confidence and reliability in the data. South Carolina's statute provides an important example of a revised reporting statute that allows for additional time for data validation prior to public reporting. Some states have found that the inclusion of patient identifiers is important to facilitate validation through processes such as chart reviews. If states choose to include patient identifiers under reporting requirements, ensuring adequate legal protections to safeguard patient confidentiality is an important consideration (see Section II).

For states using NHSN, standard internal controls are a part of system requirements, but these do not preclude the need for validation activities described above. NHSN uses standard definitions, point of entry checks, such as prohibiting entry of HAI event dates earlier than a patient admission, and periodic checks for internal consistency. Further, standard validation and risk adjustment methodologies are under development as part of CMS's Inpatient Quality Reporting Program, and thus alignment with those requirements might be considered. The focus for 2011 payment determination will require that hospitals accurately report measures using chart-abstracted data. Importantly, validated data is used for prevention and training in facilities as well as a tool for prevention collaboratives to measure impact. Some examples of state statutes requiring data validation are in Appendix I (NY, SC).

Pilot Data

States such as New York chose to collect HAI data for an initial pilot year before producing public reports. This approach ensures that appropriate risk adjustment and data validation can be established, and is helpful in achieving healthcare facility buy-in, by allowing time to make improvements before posting the first report. The latter may be particularly important for facilities who are just beginning to track and report HAI data.

New Hampshire allotted 180 days to establish a system and for hospitals to begin reporting, and an additional six month pilot phase to ensure data submitted was complete and accurate.

Reporting Implementation Timeline

Timelines for implementation of reporting requirements vary, and the experience of early adopters can inform implementation of future legislation. States that have implemented reporting programs agree that phasing in reporting measures is seen as an essential element for any state based reporting program and critical to meet the needs of stakeholders. In addition, gradually phasing public reporting of these data is suggested as well. One factor to consider is time between regulations and initiation of reporting. Many states have expressed the need to initiate reporting with facilities reporting for a full pilot year before information is disclosed to the public. During this period, assistance

will be necessary to help facilities enroll in NHSN, or other state reporting system, and validate data. If insufficient time is allotted for facilities to prepare for reporting validated data, the completeness and quality of data may be compromised giving an inaccurate picture of HAI in the state. Allowing for a pilot phase of 6-12 months as new infections are added to reporting requirements is advisable. Conversely, if requirements for reporting through CMS for a given infection (e.g., CLABSIs) are already in place, a pilot period for those infections may not be necessary.

Formats and Frequency of Public Reporting

For states that will report their HAI data publicly, it is important that regardless of data chosen to be included in the public report, the data are presented in a format that is understandable to and helpful for the public. There is wide variation in the format of public reporting provisions contained in state HAI laws and regulations, and an advisory council can be very helpful in defining how best to present information. In general, facility specific, valid, risk-adjusted reports that include numerator and denominator data should be included. Summary information with interpretation of analyses is important to include as well. An online searchable database with historical data available to track progress over time is desirable, yet states have expressed challenges in maintaining interactive databases. Some states require summary reporting by healthcare facility, while others require reporting by the state. Reports range from summaries to comprehensive medical error or quality of care reports. Some include online searchable databases. Some reports are provided from the state to the legislature to show progress and impact of the program, while some are placed on the Web for public consumption. Rates and ratios provide different ways to display the data.

Several states (AL, AR, CA, CT, CO, FL, IL, NH, NY) require HAI data to be risk adjusted in their public reports to account for patient and practice variation among facilities. Some examples of existing language requiring risk adjustment are listed in Appendix II (AL, AR, CA).

Frequency of public reporting is highly variable, ranging from no time period being specified to reports being required quarterly, semi-annually, annually, or bi-annually. Within facilities, on-going HAI reports to target prevention efforts are desirable. For states that choose NHSN for a reporting system, data are available to facilities for prevention at any time. As states consider options for public reporting timelines, factoring in adequate time to validate and risk adjust data will be needed. Quarterly reports for CMS' pay-for-reporting program will be required, so harmonization with that schedule for reporting may be desirable. Health agencies have expressed concern with the burden of publicly posting data more than once a year. Because preparation of public reports is highly time-intensive for health agency staff, consideration should be given to require posting of public reports no more frequent than annually; although reporting by healthcare facilities to the state health agency should occur more frequently. This arrangement will allow for facilities and health agencies to focus primary attention on prevention activities while still providing annual updates to the public.

Pathogen Specific Legislation

Several states have passed legislation that requires reporting of specific high-risk pathogens such as MRSA or *Clostridium difficile,* and for hospitals to implement procedures for MRSA screening and prevention. While pathogen-specific approaches can be useful, the critical objective is to prevent

transmission and infection from all pathogens. If states consider developing pathogen specific legislation, it should be part of a comprehensive HAI prevention program that sets targets and measures for prevention. Mandating the use of specific infection control practices through legislation can be problematic because of the emergence of new high-risk pathogens and evolving science that changes recommended practices and prevention strategies. To allow flexibility to respond to new scientific advancements without revisiting legislation, states are cautioned on mandating specific infection control practices within statutes and instead may choose to reference adherence to existing CDC guidelines for management of specific pathogens in healthcare.

Creative Options for Financing an HAI Program

Nevada directs funds obtained from penalties to HAI education and training.

New Hampshire established a hospital fee structure to fund the HAI program. The rule implementing this provision goes into effect July 2011.

New York authorizes the health agency to make grants to hospitals within appropriated amounts. With state resources, the health agency funds HAI prevention projects.

Washington establishes a hospital infection control grant account for infection control and surveillance programs.

Financial Support

It is recommended that funding of state programs be addressed in legislation. States should consider specifying financial support in their policies including, if possible: provisions for funding, or contingencies for actions to be delayed or not taken if funding is not made available; and establishing financial support via fees, penalty funds, or program grants, if state appropriations are not available.

States should ensure that there is sufficient flexibility to use funds for HAI prevention and complementary initiatives. States may also consider increasing licensing fees, as done in Oklahoma, or using funds generated by penalties. Use of fees or fines is an innovative approach to fund HAI prevention, but states need to consider whether this alone will sustain the program. Use of fines may be most beneficial and least controversial when fines are directed back to HAI prevention at violating facilities because it provides an incentive for facilities to ask for assistance when needed. Another option is to include setting-specific funds such as Medicaid nursing facility penalty funds that support HAI prevention in those facilities.

HAI efforts may also be supported under the umbrella of integrated public health initiatives such as expansion of electronic health records and healthcare information technology across the healthcare setting. Because CDC maintains NHSN, use of this system for state reporting mandates will continue to offer states a cost savings on HAI reporting and technical assistance compared to having to establish and maintain a separate reporting system.

Establishing an Advisory Council

Advisory councils are an essential resource for initiating and sustaining successful state HAI programs. The critical role of an advisory council is to provide guidance on the implementation of state HAI prevention and reporting programs. As a result of existing state laws and ARRA funding, all states likely have some form of HAI advisory council. It is recommended to include broad provisions to create an

advisory council in the state HAI law, thereby allowing the council to adapt its procedures as necessary through agency rulemaking or general operations.

Advisory Council Membership and Operations

Most state laws assign the state health agency to appoint members of the advisory council. This is a preferred approach to ensure that the HAI program is tightly linked with advisory council activities.

Generally, advisory councils report to the agency, body, or official that appoints them. Advisory councils advise, assist, make recommendations, and submit reports to these appointing agencies (see "Advisory Council Responsibilities").

To ensure adequate representation on advisory councils, it is important to specify membership criteria in statute or regulation. Advisory councils should include relevant stakeholders to promote HAI prevention including public health and medical professionals, state hospital associations or other hospital groups, consumers, Medicare Quality Improvement Organizations (QIO), state Association for Professionals in Infection Control and Epidemiology (APIC) chapters, healthcare epidemiologists, and other appropriate stakeholders. Joint representation by the regulatory and public health sides of the state health agency may also be necessary to promote effective prevention and help facilitate collaboration. Increasingly, care is delivered outside of hospitals and consideration for how states will prevent HAI across the spectrum of care can be informed by allowing flexibility in advisory council membership. For example, it may become important to include members who represent types of healthcare settings or types of procedures at risk for HAI such as dialysis centers, long term care facilities, laboratories, medical professional organizations, or AARP. There should be flexibility to add membership as needed. Experience also suggests it is beneficial for the advisory council to be of a reasonable size to facilitate decision making.

When funding for advisory council member travel is unavailable, alternative arrangements such as webinars have been used in Tennessee and other states.

To ensure that advisory councils have appropriate representation to carry out their duties, reimbursement for expenses facilitates broad participation, especially for consumers. Alabama, California, and Texas statutes allow for subcommittee creation. This approach could be a valuable tool to respond to emerging threats from HAI, and allowing for experts outside of the council members to participate as needed in subcommittee work can facilitate broad discussion of issues. To keep advisory council work from stagnating due to absenteeism, proxy voting and alternate members are advisable. Lastly, meeting timelines should align with reporting timelines so that advisory councils can effectively fulfill their responsibilities (see below).

Advisory councils must be able to respond to changing needs and priorities of the state HAI program. Overly prescriptive language will limit the flexibility needed to do so. Establishing advisory councils as a rulemaking body may not be desirable due to excess administrative burden and to avoid duplicating existing health agency authority.

Advisory Council Responsibilities

It is important to distinguish the roles of the advisory council and the health agency. The health agency should have authority to make final decisions and implement the HAI program independently of the advisory council. It is recommended for the advisory councils to "advise" the state health agency. While the advisory council should have a broad scope of responsibilities to all pertinent HAI reporting and prevention issues, the decision-making authority remains with the health agency.

Tennessee provides a good model for interaction between the health agency and advisory council. The state health agency provides progress reports to the advisory council and the council provides input into the state HAI action plan and strategies to meet goals.

Advisory councils can be useful in assisting health agencies in defining and implementing reporting programs. They can:

- Advise on collection, analysis, and dissemination of HAI data, often requiring consideration or adoption of national standards or NHSN.
- Determine additional reporting measures as appropriate (NH, NY).
- Recommend standard definitions, measures, criteria, or methods.
- Evaluate the quality and accuracy of facility data or establish a process for this evaluation.
- Prepare reports or determine methods for sharing reports with the public.
- Review draft regulations, legislation, and other items of importance to HAI prevention (e.g., CMS IPPS rule, Council of State and Territorial Epidemiologists HAI reporting standards).

Some state laws require the advisory council to address staff or public education regarding HAI, and advisory councils may be well positioned to address training more broadly.

Financial Incentives

Whenever possible, states are encouraged to choose incentives to encourage compliance over disincentives for discouraging non-compliance to help promote a culture of safety and proactive HAI prevention approaches. However, financial incentives for good performers may still leave poor performers without resources to invest in improvements. It is important to offer support to improve simultaneously those that are not doing as well while encouraging and rewarding good performers.

Some states have undertaken innovative ways to use financial incentives to promote HAI prevention including subsidies to offset costs that providers incur for updating electronic data systems, and increases in reimbursement rates for providers that meet HAI reduction targets. For example, Pennsylvania awards a quality improvement payment to facilities that meet a benchmark for percent reduction in HAI, which is funded through state appropriations. The inclusion of third party payer incentives has important implications for advancing prevention, as not all hospitals are covered by Medicare and the IPPS incentive to report valid HAI data. Tennessee requires participation in a collaborative for hospitals to be included in the state employee health insurance contract thus linking prevention and payment. These are encouraging trends in states.

There are also examples of incentives that are not explicitly financial. For example, "peer pressure" may incentivize providers to meet HAI reduction goals simply through public reporting of facility specific data. High performers can publicize the quality of services to customers, while low performers can be targeted by health agencies for assistance.

Licensure

Infection control requirements for facility licensure and professional accreditation of staff can assist in improving HAI prevention and patient safety. The health agency may have unique authority to ensure compliance with safety standards that cannot be as effectively managed by a licensing board. When considering the following provisions, states need to weigh the benefits of each option with potential unintended consequences, such as reluctance among facilities to promptly report problems for fear of repercussions or damage to the health agency and healthcare facility relationship. In some cases, the measures described below may be necessary to ensure compliance with infection control policies and protect patient safety; however, the primary goal is to create a culture of safety throughout the state. States are advised to engage their key partners and stakeholders in drafting these and other HAI policy provisions, to ensure optimal buy-in and support for implementation.

Requirements for licensure can promote positive actions and to dissuade negative actions. In some states, participation in HAI reporting systems or prevention programs is a condition of licensure. As a result, non-compliance may be associated with denial, suspension, or revocation of licensure. The definition of non-compliance is also important, as states can opt to go beyond defining compliance as just reporting data, and instead require reporting of *validated* data (e.g., New York) or conducting prevention activities. Associating sanctions for certain practices can provide health agencies authority to better ensure patient safety.

States should consider, in confidentiality and privilege provisions, how reported data will be used for licensure purposes and ensure that there is authority to use the data for sanctions when necessary. To sanction staff or facilities requires the ability to disclose data to the licensing board. However, disclosure of data should be limited sufficiently to maintain a trustful partnership for HAI prevention between the health agency and facilities (e.g., disclose only for severe violations or "never events").

Including the ability to issue permits for certain procedures and to inspect non-licensed settings in state authority is important for HAI prevention, as increasingly complex procedures are performed in a variety of healthcare settings. For example, Nevada has implemented permitting requirements to ensure compliance on the use of anesthesia. Permitting for procedures or practices is a valuable tool in the rapidly changing healthcare environment. In addition to statutory provisions, states have successfully used regulation to increase HAI prevention through licensure. New Jersey and Nevada have enhanced authority to regulate ambulatory settings. New Jersey regulation requires licensed ambulatory care facilities to have, on staff, an expert in HAI and a certified infection control professional.

Associating fines or denial or revocation of licensure as measures for non-compliance with licensure provisions is also a disincentive at the staffing level. For example, some states routinely notify medical boards of egregious outbreaks in private doctor offices and clinics. Including infection control

requirements for continuing medical education can be more strictly enforced via licensure. For example, in New York, healthcare providers must receive infection control and barrier precaution training every four years in order to renew their licenses. Similarly, there may be a mechanism under licensure to sanction individual staff for unsafe practices with regard to HAI. Like with other means of oversight, licensing enforcement should also include a process for modification after the violation.

The type of law in which the HAI statute is included has significance. Amending the licensure codes may be a viable option (rather than the state public health act), but it may also be problematic to pass if businesses are in opposition to additional oversight. It may also be problematic to implement if the health agency wants to expand oversight to non-licensed settings. It is important to emphasize that HAI also occur in non-licensed settings, but in most states these settings fall outside of reporting, prevention, and oversight authorities.

CME Opportunities

States may wish to examine CME (Continuing Medical Education) requirements for state licensure as an opportunity to advance HAI education and training. In Colorado, staff that collect HAI data in hospitals with more than 50 beds must become certified in infection control. In California, each hospital epidemiologist or infection control physician must receive CME through CDC, SHEA, or another recognized organization, while the advisory council recommends training curriculum and methods for other staff. In California, certification includes: documentation of CME attendance in credentialing file for the epidemiologist/infection control physician, and observation of environmental staff for compliance with hospital sanitation measures.

Training Requirements

Even with training resources provided through professional organizations (e.g., APIC, SHEA) and federal and state agencies, a lack of requirements in statute or regulation may contribute to inadequate HAI training for healthcare professionals.

States have greater flexibility when HAI law grants the health agency authority to determine training requirements in regulation as opposed to statute. For example, Tennessee Department of Health rules and regulations require facilities to provide hand hygiene education to staff and document the impact by measuring hand hygiene practices.

Every healthcare professional should receive HAI prevention education and training. Many medical and nursing schools include infection control in their curriculum. New York law requires healthcare professionals and students to receive routine infection control training prior to licensure. Documentation and follow up is necessary to ensure training is sustained beyond the period of program initiation. Some states use certification or other methods to enforce training requirements.

Training is provided through a variety of mechanisms. In at least four states, facilities are expected to implement education and training on topics such as hand hygiene education, MRSA transmission, infection control, and preventive measures. In more than one state, the hospital prevention program is statutorily required to provide staff education on HAI prevention. The New York State Health

Department trains facilities statewide on HAI prevention and NHSN reporting. This initiative has served as a model for other states, including South Carolina and New Hampshire.

In establishing training requirements, it is important to consider how they will be funded. Innovative approaches can promote sustainability of HAI training efforts. Nevada uses funds from administrative sanctions to cover the costs for staff training and public education on provision of quality healthcare. Online training can also reduce training costs. ARRA funds have been used to cover training for health agency staff, NHSN user training, and prevention training through the hospital prevention collaborative.

Health Agency Staff

Continuing education on HAI for health agency staff is also needed. Training should address the range of skills needed to accomplish all HAI program goals. In California, the health agency and advisory council work hand-in-hand to ensure both health agency and facility staff are trained on NHSN and HAI prevention. California addressed insufficient infection control expertise among state surveyors by allowing the health agency to hire consultants. Some states work with APIC chapters for consulting services and training. The Council of State and Territorial Epidemiologists (CSTE), in collaboration with CDC, supports recent graduates with two years of training at a state health agency under the guidance of an experienced mentor. In 2009, nine CSTE fellows were trained at CDC to work with state HAI coordinators to support HAI prevention activities. In addition, Occupational Safety and Health Administration (OSHA) education centers and state occupational safety and health programs offer courses and videos on blood borne pathogens. The Society for Healthcare Epidemiology of America (SHEA), in collaboration with CDC, has developed a Regional HAI Train-The-Trainer program all state HAI Coordinators to provide them with the materials necessary to implement in each of their respective states to address infection control practices.

Financial Disincentives for Non-Compliance, Penalties, and Corrective Measures

Financial disincentives are triggered when facilities fail to report (e.g., required data, sentinel events), experience an avoidable sentinel event, fail to show progress in reducing an infection rate, or do not follow provisions of the law. Funds generated from disincentives can be used to fund HAI prevention programs and incentive programs.

Key elements for financial disincentives can include:

- Consider what will trigger a penalty – not reporting valid data, failure to follow evidence-based practices, continued failure to meet a certain benchmark, etc.

Nevada's statute provides a detailed example of financial disincentives imposed for failure to report a sentinel event, failure to adopt and implement a patient safety plan, failure to establish a patient safety committee, or failure for the committee to meet certain requirements. The statute details the process that must be followed if a healthcare provider or facility is found to have significantly contributed to a case of infectious disease or exposure to a biological agent, or if a facility violates any provision related to its licensure. These processes must be followed before an administrative sanction can be imposed. The statute also establishes a minimum and maximum penalty that may be charged per patient, which is recommended.

- Financial disincentives should be in statute – include a cap in the statute and outline the details in regulation.

Other states, including Delaware, include a penalty cap of the highest amount that may be imposed in statute, but use regulation for details of implementation. The statute states: "[a] determination that a hospital or correctional facility has violated the provisions of this Act may result in a civil penalty of up to $500 per day per violation for each day the hospital or correctional facility is in violation of this Act."

- Consider amending insurance code to allow private insurance companies to adopt the Medicare non-payment policy.

Some states, such as South Carolina, have amended or are considering amending state insurance code to allow private insurance companies to adopt a Medicare non-payment policy. This is particularly relevant for healthcare settings not reimbursed by CMS, but by third party payers.

Process for Modification after Violation

States should consider providing in statute the authority for health agencies to require a corrective action plan once a violation has occurred or an entity has failed to meet a benchmark. Such provisions may set forth a process for developing corrective action plans, implementing those plans, assessing if the correction has been effective, and if not, what actions will then be taken. The statute should provide flexibility to allow for legal due process requirements and any future modifications.

IV. CONCLUSION

Healthcare-associated infections (HAI) are a critical challenge to public health in the United States as a significant cause of death, and are preventable. State health agencies have a central role to play in HAI elimination because they are responsible for protection of patients across the healthcare system and serve as a bridge between healthcare and the community. Despite current progress towards the elimination of HAI, there is much work to be done to sustain state HAI prevention programs. Legal and policy interventions can help accelerate HAI prevention through implementation of a public health model that promotes adherence to evidence-based practices and uses valid data to respond to emerging threats and focus prevention efforts. State regulatory and oversight tools are additional levers for effective HAI prevention that can be implemented in both hospital and non-hospital settings. States are currently creating or expanding effective HAI laws and policies. For HAI elimination to succeed, each state will need to implement appropriate state policies that may include:

- Providing incentives for HAI prevention.
- Increasing survey and certification activities across the spectrum of care.
- Implementing licensure and training requirements.
- Increasing adherence of healthcare facilities and providers to infection control recommendations.
- Implementing or expanding public reporting.
- Ensuring appropriate regulatory oversight.

For those states pursuing policy change, ensuring that appropriate state statutory, regulatory and administrative tools are in place provides a foundation to accelerate HAI elimination for now and for generations to come.

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APPENDIX I: Table of Authorities

Statutes Relating to State HAI Programs

State	HAI Authority
AL	ALA. CODE § 22-11A-110 et seq. (2011). - http://alisondb.legislature.state.al.us/acas/CodeOfAlabama/1975/125823.htm
AR	ARK. CODE ANN. § 20-9-1201 et seq. (West 2011). - http://www.lexisnexis.com/hottopics/arcode/Default.asp
CA[iv]	CAL.HEALTH & SAFETY CODE § 1288.45 et seq. (West 2011). - http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=01001-02000&file=1288.45-1288.9
CO[v]	COLO. REV. STAT. ANN. § 25-3-601 et seq. (2011). - http://www.michie.com/colorado/lpext.dll?f=FifLink&t=document-frame.htm&l=jump&iid=115d17d4.210a391e.0.0&nid=136b1#JD_t25art3p6
CT	CONN. GEN. STAT. § 19a-490n, o, p (2011). - http://www.cga.ct.gov/2009/pub/chap368v.htm#Sec19a-490n.htm
DC	D.C. CODE § 7-161 (2011). - http://www.michie.com/dc/lpext.dll/dccode/41b/5601/5603/5605/5685/5687?fn=document-frame.htm&f=templates&2.0#
DE	DEL. CODE ANN. tit. 16, § 1001A et seq. (2011) ; § 1006. - http://delcode.delaware.gov/title16/c010a/index.shtml
IL	210 Ill. Comp. Stat. §§ 86/1 to 86/45 (2008 & Supp. 2009); 210 ILCS 83/1 et seq (2011). - http://www.ilga.gov/legislation/ilcs/ilcs4.asp?DocName=002023100HArt.+2310&ActID=331&ChapterID=5&SeqStart=100000&SeqEnd=-1; - http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2919&ChapterID=21
ME[vi]	ME. REV. STAT. ANN. tit. 22, ch. 1684 § 8751 et seq.; ME. REV. STAT. ANN. tit. 22, ch. 1684-A § 8761 - http://www.mainelegislature.org/legis/statutes/22/title22sec8751.html; - http://www.mainelegislature.org/legis/statutes/22/title22sec8761.html
MD	MD. CODE ANN., HEALTH–GEN., § 19-134 (West 2011). - http://www.michie.com/maryland/lpext.dll/mdcode/12fde/14508/1450a/145c1?f=templates&fn=document-frame.htm&2.0#JD_hg19-134 -
MA[vii]	MASS. GEN. LAWS ANN. ch. 111, § 51H (2011). - http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section51H
MN	MINN. STAT. ANN. § 62J.82 (2011), MINN. STAT. ANN. § 144.585 (2011).

[iv] *See also* CAL.HEALTH & SAFETY CODE § 1279.6 (West 2011) (requiring health facilities to develop and implement patient safety plans within hospitals to educate about HAI, report their incidence, and evaluate prevention methods, as defined by CDC's NHSN, unless the HAI Advisory Committee or its successor recommend otherwise).

[v] Colorado also passed a law (signed 3/30/2009) requiring certification of persons who collect data on HAI, with exceptions for hospitals with fewer than 50 beds, ambulatory surgery centers, and dialysis centers, and NCSL categorizes this law under "MRSA." *Available at* http://www.leg.state.co.us/clics/clics2009a/csl.nsf/fsbillcont3/F2D0E32E8DAB48A687257537001BB485?open&file=1025_enr.pdf.

[vi] *See also* Resolve, Requiring Rulemaking by the Maine Health Data Organization in Consultation with the Maine Quality Forum Regarding Clostridium Difficile and Methicillin-resistant Staphylococcus Aureus, *available at* http://www.mainelegislature.org/legis/bills/bills_124th/chappdfs/RESOLVE82.pdf.

[vii] *See also* MASS. GEN. LAWS ANN. ch. 6A, § 16K (2011) (instituting the Maryland Healthcare Quality and Cost Council that shall adopt a reporting plan on quality and cost measures, including an updated website with information at least annually reported "to the extent possible" on data concerning HAI and serious reportable events).

State	HAI Authority
	- https://www.revisor.mn.gov/statutes/?id=62J.82; - https://www.revisor.mn.gov/statutes/?id=144.585
MO	MO. ANN. STAT. 192.667 (West 2011); MO. ANN. STAT. 192.131 (West 2011). - http://www.moga.mo.gov/statutes/C100-199/1920000131.HTM; - http://www.moga.mo.gov/statutes/C100-199/1920000667.HTM
NV	NEV. REV. STAT. ch. 439, 441A, 449. - http://www.leg.state.nv.us/NRS/NRS-439.html#NRS439Sec800 - http://www.leg.state.nv.us/NRS/NRS-441A.html - http://www.leg.state.nv.us/NRS/NRS-449.html
NH	N.H. REV. STAT. ANN. § 151:32 et seq. - http://www.gencourt.state.nh.us/rsa/html/NHTOC/NHTOC-XI-151.htm
NJ	N.J. STAT. ANN. 26:2H-12.49 et seq (West 2011); N.J. Stat. Ann. §§ 26:2H-5.1e - 5.1f. - http://lis.njleg.state.nj.us/cgi-bin/om_isapi.dll?clientID=231754923&Depth=4&TD=WRAP&advquery=2H-12.45&headingswithhits=on&infobase=statutes.nfo&rank=&record={A509}&softpage=Document42&wordsaroundhits=2&x=0&y=0&zz=
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NY	N.Y. PUB. HEALTH Law § 2819 (McKinney 2011). - http://public.leginfo.state.ny.us/LAWSSEAF.cgi?QUERYTYPE=LAWS+&QUERYDATA=$$PBH2819$$@TXPBH02819+&LIST=LAW+&BROWSER=BROWSER+&TOKEN=37492244+&TARGET=VIEW
OH	OHIO REV. CODE ANN. § 3727.31 et seq (West 2011). - http://codes.ohio.gov/orc/3727
OK	OKLA. STAT. ANN. tit. 63, § 1-707 (West 2011). - http://webserver1.lsb.state.ok.us/OK_Statutes/CompleteTitles/os63.rtf
OR	OR. REV. STAT. ANN. tit. 36, Ch. 442 (see note for 442.851) - http://www.leg.state.or.us/ors/442.html
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APPENDIX II: Metrics and National 5-Year Prevention Targets in HHS Action Plan to Prevent HAI

Metric Number and Label	Original Metric	HAI Comparison Metric	Measurement System	National Baseline Established (State Baselines Established)	National 5-Year Prevention Target	Coordinator of Measurement System	NQF endorsed
1. CLABSI 1	CLABSIs per 1,000 device days by ICU and other locations	CLABSI SIR	NHSN Device-Associated Module	2006-2008 (proposed 2009, in consultation with states)	At least 50% reduction in central line-associated bloodstream infections in ICU and ward-located patients	CDC	Yes*
2. CLIP 1 (formerly CLABSI 4)	Central line bundle compliance (non-emergent insertions)	CLIP adherence percentage	NHSN CLIP in Device-Associated Module	2009 (proposed 2009, in consultation with states)	100% adherence with central line bundle	CDC	Yes†
3a. C diff 1	Case rate per patient days; administrative/ discharge data for ICD-9 CM coded *C. difficile* Infections	Hospitalizations with *C. difficile* per 1,000 patient discharges	Hospital discharge data	2008 (proposed 2008, in consultation with states)	At least 30% reduction in hospitalizations with *C. difficile* per 1,000 patient discharges	AHRQ or CDC	No
3b. C diff 2 (new)		*C. difficile* SIR	CDC NHSN MDRO/CDAD Module LabID‡	2009-2010	Reduce the facility-wide healthcare facility-onset *C. difficile* LabID event SIR by at least 30% from baseline	CDC	No
4. CAUTI 2	# of symptomatic UTI per 1,000 urinary catheter days	CAUTI SIR	CDC NHSN Device-Associated Module	2009 for ICUs and other locations 2009 for other hospital units (proposed 2009, in consultation with states)	Reduce the CAUTI SIR by at least 25% from baseline in ICU and other locations	CDC	Yes*
5a. MRSA 1	Incidence rate (number per 100,000 persons) of invasive MRSA infections	MRSA incidence rate (healthcare-associated)	CDC EIP/ABCs	2007-2008 (for non-EIP states, MRSA metric to be developed in collaboration with EIP states)	At least a 50% reduction in incidence of healthcare-associated invasive MRSA infections	CDC	No
5b. MRSA 2 (new)		MRSA bacteremia SIR	CDC NHSN MDRO/CDAD Module LabID‡	2009-2010	Reduce the facility-wide healthcare facility-onset MRSA bacteremia LabID event SIR by at least 25% from baseline	CDC	No
6. SSI 1	Deep incision and organ space infection rates using NHSN	SSI SIR	CDC NHSN Procedure-Associated Module	2006-2008 (proposed 2009, in consultation with states)	Reduce the admission and readmission SSI§ SIR by at least 25%	CDC	Yes¶

	definitions (SCIP procedures)				from baseline		
7. SCIP 1 (formerly SSI 2)	Adherence to SCIP/NQF infection process measures	SCIP adherence percentage	CMS SCIP	To be determined by CMS	At least 95% adherence to process measures to prevent surgical site infections	CMS	Yes

* NHSN SIR metric is derived from NQF-endorsed metric data.
† NHSN does not collect information on daily review of line necessity, which is part of the NQF.
‡ LabID, events reported through laboratory detection methods that produce proxy measures for infection surveillance.
§ Inclusion of SSI events detected on admission and readmission reduces potential bias introduced by variability in post-discharge surveillance efforts.
¶ The NQF-endorsed metric includes deep wound and organ space SSIs only which are included the target.

APPENDIX III: Summary of Toolkit Recommendations

Reporting of Healthcare-Associated Infections

- Define how reporting of HAI will be used in your state (facility safety and quality improvement, public health and epidemiologic use, or public reporting).
- Determine if reporting should be mandatory. If so, what facilities should be required to report and what will be reported, considering process measures and reporting of infections from different locations within facilities.
- Consider using NHSN for the data collection system.
- Develop a strategy for data validation.
- Define formats and frequency of public reporting.
- Consider timelines for implementation of reporting, with a gradual phasing of public reporting of data recommended.
- If reporting is mandated, consider linking reporting requirements to other HAI regulations.

Financial Support

- Identify funding implications for HAI reporting and prevention.
- Specify funding provisions or potential mechanisms.
- Establish financial support via fees, penalty funds, or program grants.
- Consider including language with contingencies for lack of funding.

Advisory Councils

- Assign the health agency to appoint experts, consumers, and key stakeholders.
- Allow for flexibility to add members as needed.
- Consider local context when establishing and refining the council in statute, regulation or at the program level.
- Establish only broad parameters for operations, allowing the council to adapt through use of agency rulemaking or general operations.
- Broaden scope of council to all pertinent HAI reporting and prevention issues, but ensure decision making authority remains with the health agency.

Financial Incentives

- Establish financial incentives such as subsidies for facility reporting costs, increased reimbursement, and quality improvement payments.
- Consider how third party payers can be engaged (e.g., quality improvement payments).
- Promote improvement and continued success.
- Target poor performers for HAI prevention assistance and to foster improvement.

Licensure

- Expand licensing authority as appropriate to require HAI reporting and prevention.

- Define requirements that promote prevention, and allow for fines or license denial or revocation for non-compliance.
- Expand health agency authority as appropriate, including to inspect non-licensed and ambulatory settings.
- Ensure that confidentiality provisions allow for use of reported data for licensure purposes.
- Consider opportunities to promote HAI prevention through staff licensure (e.g., infection control training).

Training

- Allow the health agency the authority to determine requirements in regulation.
- Consider use of existing mechanisms to require HAI training (e.g., medical and nursing schools, CME, licensure requirements).
- Ensure trainers (facilities, the health agency, or contracted trainers) have the capacity and expertise necessary to train facilities on reporting and prevention.
- Maximize existing expertise (e.g., consultants, APIC chapters, advisory council).
- Consider innovative and sustainable funding mechanisms for training.
- Set the goal of having all healthcare professionals trained in HAI prevention and patient training.

Financial Disincentives

- Consider what will trigger a penalty – not reporting valid data, not meeting a certain benchmark, etc.
- Financial disincentives should be in statute – include a cap in the statute and outline the details in regulation.
- Consider amending insurance code to allow private insurance companies to adopt the Medicare non-payment policy.

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