

# The Legal Landscape: HAI Public Reporting in the United States

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## LEARNING OBJECTIVES:

1. Discuss the role of federal influences on state-level HAI program initiatives and reporting activities.
2. Describe the progression of state-level initiatives to reduce HAIs from 2004 to the current date.
3. Describe core provisions of state HAI reporting laws: surveillance, collection system, healthcare settings subject to the laws, types of infections reported, public reporting requirements, and advisory committee structure.
4. Identify healthcare worker infection and illness reporting mandates.

**ABBREVIATIONS:** ACA – The Patient Protection and Affordable Care Act, CDC – Centers for Disease Control and Prevention, CMS – Centers for Medicare and Medicaid Services, CLABSI – central line-associated bloodstream infection, CAUTI – catheter-associated urinary tract infection, CRE – Carbenem-resistant Enterobacteriaceae, HAIs – healthcare-associated infections, HHS – U.S. Department of Health and Human Services, IQR – Inpatient Quality Reporting Program, MRSA -- Methicillin Resistant *Staphylococcus aureus*, NHSN – National Healthcare Safety Network, OSHA – Occupational Safety and Health Administration, VAP – ventilator-associated pneumonia

**INDEX TERMS:** Healthcare-associated Infections, HAI, Antibiotic Resistance, *C. difficile*, CDI, Healthcare Worker Safety, Multiple Drug Resistant Organisms, Patient Safety, Patient Protection and Affordable Care Act, Affordable Care Act, ACA, Law, Inpatient Quality Reporting Program, National Healthcare Safety Network, Surveillance.

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## INTRODUCTION

Since early 2000, there has been a “growing interest in the use of law as a tool to address” healthcare-associated infections (HAIs) in the U.S.<sup>1</sup> All 50 states and two territories have HAI programs established within their public health agencies.<sup>2</sup> Likewise, the majority of states have HAI public reporting laws.<sup>3-4</sup> HAI data is being reported from hospitals in all 50 states, either voluntarily or under state or federal legal reporting mandates.<sup>5</sup> Additionally, while the current national focus is on reporting HAIs in the patient population, requirements for reporting infections and illness in the healthcare worker population also exists. The purpose of

this article is to provide a review of the federal and state-level legal environment applicable to HAI prevention in the context of the overall response to HAIs.

### Federal Influences

To fully grasp state-level HAI program initiatives and reporting activities, it is important first to understand the many federal influences. Through the U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), the federal government plays a central role in the control and prevention of HAIs. From 2004 to 2008, states began to recognize the need for state policies aimed at HAI prevention.<sup>4</sup> Several states made significant strides toward HAI surveillance and prevention as the awareness of the public health impact of HAIs grew. However, due to budget constraints and the associated poor economic conditions starting in 2008, most states were unable to implement or further develop their HAI programs. Significant improvements occurred in 2009 when HHS and CDC began to provide federal funding, guidance, and other resources to support state HAI programs.<sup>4</sup>

Since 2009, HHS has consistently provided significant funding for state HAI prevention and infrastructure. Funding was initially provided under the American Recovery and Reinvestment Act, followed by awards from the Patient Protection and Affordable Care Act (ACA).<sup>6,7</sup> Federal funding has been earmarked for specific HAI activities. For example, 2014 funding supported state HAI infrastructure; antimicrobial stewardship; prevention of *Clostridium difficile*, Carbapenem-resistant Enterobacteriaceae (CRE), and hemodialysis bloodstream infections; HAI data validation; and promotion of safe injection practices.<sup>7</sup> Many have considered the federal funding a critical resource for the development and proper functioning of state HAI programs. Indeed, findings of a recent study by the CDC and Rand Corporation suggest that state-level HAI program growth has improved as a result of federal funding.<sup>8</sup>

Federal HAI prevention goals are outlined in the HHS' National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination (HAI Action Plan).<sup>9</sup> To receive federal funding, each state was required to create a plan describing how it planned to address HAIs within its jurisdiction. The first phase of

this plan was released to the states in 2009 and focused on infections of acute care inpatient settings.<sup>9</sup> Two updated phases applicable to outpatient settings, influenza vaccination of health care personnel, and long-term care facilities have been subsequently released.<sup>9</sup>

Although most HAI data reporting occurs on the state level, federal reporting requirements also exist. Federal reporting of HAIs by hospitals is required under the Centers for Medicare and Medicaid Services (CMS) Inpatient Quality Reporting Program (IQR Program).<sup>10</sup> The IQR Program, which began in 2010, was developed under the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Deficit Reduction Act added new requirements.<sup>10</sup> Medicare certified facilities ("sub-section (d)" hospitals) are required to submit data on specific quality measures, including HAIs, to receive full reimbursement.<sup>10</sup>

Federal HAI reporting requirements under the IQR program have been phased in since January 2011, beginning with central line-associated bloodstream infections (CLABSI) in adult, pediatric, and neonatal intensive care units. Additional reportable infections have been added since that time.<sup>11</sup>

Reporting mandates have also been established under the Hospital Outpatient Quality Reporting Program, End Stage Renal Disease Quality Incentive Program, Long Term Care Hospital Quality Reporting Program, and Inpatient Rehabilitation Facility Quality Reporting Program.<sup>11</sup> Similar to the mandates of the IQR program requirements, the infections required to be reported under these other programs have been phased in over time.

Collection of HAI data is accomplished via the CDC's National Healthcare Safety Network (NHSN). The NHSN, "the nation's most widely used [HAI] tracking system", is used for the purpose of reporting HAI data under both state and federal mandates.<sup>12</sup> The system currently serves over 13,000 medical facilities.<sup>13</sup> The CDC plans on expanding the NHSN to more than 17,000 facilities in 2016. As part of that plan, the CDC will continue its efforts to work with state and local health departments to assist with NHSN data collection and implementation of prevention strategies.<sup>14</sup>

Facilities participating in the IQR Program are required to utilize the NHSN for reporting HAI data. Hospitals must enroll in the program and complete NHSN training to comply with these federal regulations.<sup>15</sup> After HAI data is collected, it is publicly reported on a federal website called Hospital Compare.<sup>10</sup>

### State HAI Programs and Laws

State-level initiatives to prevent and reduce the incidence of HAIs began around 2003 to 2004.<sup>4</sup> Since that time, state HAI initiatives have increased.<sup>4</sup> Currently, all states and some territories have programs to manage HAI surveillance, public reporting, and prevention efforts.<sup>2</sup> Some of these state HAI programs began in 2009 or 2010; thus, it can be presumed that the influx of federal funding and guidance has positively influenced the development of these state programs.<sup>4</sup>

Running concurrently with the development of state HAI programs, there has been a steady progression in the number of states that have enacted HAI statutes and/or promulgated administrative regulations. A few states enacted HAI laws as early as 2004.<sup>4</sup> By 2008, the number had grown to 23 states.<sup>16</sup> In 2011, there were 34 states with HAI laws (including 2 U.S. territories), and that number had grown to 37 by January 2013.<sup>3-4</sup>

State HAI laws are heavily dependent on surveillance. Surveillance is achieved through data submission by hospitals and other facilities subject to the laws. On the state level, data submission requirements may be mandatory or voluntary; the vast majority are mandatory.<sup>3</sup> Also, some states incorporate federal CMS quality reporting regulations into the state HAI law. Under these laws, healthcare facilities must report data using federal requirements and timelines. Most states use NHSN as the preferred data collection surveillance system.<sup>4</sup>

For states without HAI laws, submission of HAI data and participation by facilities in the HAI state program is entirely voluntary.<sup>3</sup> It is also important to recognize that many states with HAI public reporting laws with mandatory data submission requirements for certain infections may also have voluntary surveillance initiatives for other infections.

HAIs can occur in various types of healthcare settings. However, only certain facilities will be subject to

reporting requirements.<sup>17</sup> For example, HAIs are known to occur in general and acute care hospitals, ambulatory surgical centers, outpatient care clinics, dialysis centers, and rehabilitation centers. They also frequently occur in long-term care facilities such as nursing homes and skilled nursing facilities. Despite the occurrence of HAIs in these numerous facilities, considerable variation in reporting exists across the states since each state HAI law designates which type or types of healthcare facilities are subject to the law.<sup>17</sup>

Similarly, although a variety of infection types may be contracted by patients during the delivery of healthcare, only certain types are commonly required to be reported under HAI laws.<sup>17-18</sup> Many state HAI laws mandate reporting of infections associated with invasive devices used in medical procedures such as CLABSI, catheter-associated urinary tract infections (CAUTI), and ventilator-associated pneumonia (VAP).<sup>17-19</sup> Of the device-associated infections, most states with HAI laws require data submission of CLABSI infections occurring in hospitals, followed by CAUTI, and then VAP.<sup>4</sup> Reporting of surgical site infections is also commonly required under state mandates, particularly infections related to abdominal hysterectomies and colon surgeries.<sup>5,20</sup> Reporting mandates for laboratory-identified hospital-onset *Clostridium difficile* infections have gradually increased since 2008, and reporting of Methicillin Resistant *Staphylococcus aureus* (MRSA) bacteremia laboratory identified hospital-onset bloodstream infections is also reportable under many state laws.<sup>5,21,22</sup>

The public reporting components of HAI laws are essential for promoting facility transparency and accountability. After an analysis of data by the state HAI program, it is “publicly reported” by various means, usually by annual reports or searchable databases. This publicly released information details the rates of HAIs (typically by naming the facilities and the associated infection rates) so that consumers can use the information to make informed choices about healthcare.<sup>3</sup>

State level advisory committees are an integral component of state HAI public reporting programs. According to the latest CDC HAI progress report, “[f]ull engagement between local, state and federal public health agencies and their partners in the

healthcare sector [is] vital to sustaining and extending HAI surveillance and prevention progress.”<sup>5</sup> Established as part of the state HAI initiative, advisory groups provide significant contributions by providing expert-level guidance and decision-making. They work in tandem with the state health department on the implementation, ongoing management, and policy setting functions of the state HAI program.

Many HAI public reporting laws provide for the creation of a HAI advisory committee or council within the statute itself. The laws are usually very specific in designating membership requirements, presenting the meeting schedules, and setting the general duties, requirements, authority and powers of the committees. Like other HAI law provisions, these provisions are quite variable from state to state; however, the overall common goal is to provide for a multidisciplinary advisory council to advise the state on HAI best practices and policy issues. States without HAI laws also have advisory committees, many of which were created in response to the requirements of the HAI Action Plan.

Partners and stakeholders involved in advisory committees come from common groups. Quite frequently each state will partner with a local academic center. Other partners commonly involved in the advisory committee or as partners in other HAI program endeavors include the state Quality Improvement Organization, the state hospital association, and local advocacy or consumer groups. Professional organizations are also heavily involved in the goals of monitoring and preventing HAIs. Organizations such as the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, and the Association for Professionals in Infection Control frequently have representatives who either serve on the state advisory committee or are otherwise heavily involved in state HAI prevention collaboratives.

### Healthcare Worker Infections

The recent cases of Ebola in Dallas, Texas, ongoing infections with bloodborne pathogens, as well as colonization and infection with MRSA in worker populations reminds us that infections associated with healthcare also impact healthcare workers. Just as reporting patient infections is important to identify, treat, and prevent further transmission, so is reporting

healthcare worker infections.

Although much attention has been given to reporting of HAIs in patient populations, reporting infections in the healthcare worker population is also mandated by law. Occupational Safety and Health Administration (OSHA) regulations contain recordkeeping and reporting requirements for worker infections or “occupationally acquired infections.”<sup>23</sup> Infections or illnesses required to be recorded include those associated with bloodborne, airborne, and contact transmissible pathogens. As part of NHSN support mentioned above, the CDC also has guidance in place for reporting occupational infections in its Healthcare Personnel Exposure Module.<sup>24</sup>

State requirements for reporting worker infections also exist. These additional requirements are can be found in OSHA State Plans created by State Departments of Health.<sup>25</sup> These requirements often include occupational illness or infection reporting and vaccination compliance as a condition of hospital licensure and certification.

### CONCLUSION

Currently, all U.S. states have HAI public reporting and prevention programs established within their public health agencies. The majority of these states have also enacted HAI public reporting laws. Healthcare worker infections and illness are also reportable on the state level. State initiatives are further augmented by federal reporting mandates, funding, NHSN surveillance support, and other guidance. These combined efforts represent a significant level of increased state and federal activity to address the impact of HAIs in our U.S. healthcare system.

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