The Emergence of Law to Address Healthcare-Associated Infections

By Tara Ramanathan, JD, MPH and Matthew Penn, JD, MLIS

Introduction

This article seeks to call attention to resources describing the body of state and federal law that may assist the healthcare and public health sectors to reduce the burden of healthcare-associated infections (HAIs). Depending on their practice, attorneys advising health professionals and facilities, patient advocates, and governmental clients around the country will recognize the relevance of HAIs to their clients. HAIs are infections that occur during the course of healthcare delivery, affecting 1 in 20 patients in U.S. hospitals.[1] While many HAIs are associated with devices used in medical procedures, such as catheters or ventilators, other infections may occur at surgery sites or from contact with contaminated surfaces.[2] Economic analyses conducted at the Centers for Disease Control and Prevention (CDC) report that HAIs in hospitals alone result in up to $33 billion in excess medical costs every year.[3] Health lawyers should be aware of the growing interest in the use of law as a tool to address HAIs when counseling individual and institutional clients about licensure, liability, and other legal concerns.

The Burden of HAIs and the Emerging Role of Law

Health lawyers representing all manner of professionals, facilities, and interest groups will need to recognize the importance of understanding HAIs and the impact that state and federal policies may have on HAI prevention. HAIs affect more patients than ever, as healthcare is increasingly delivered in non-hospital settings, including ambulatory surgical centers, dialysis clinics, long-term care facilities, and private doctors' offices.[4] Because a single infection may be associated with a patient, his or her healthcare provider, the facility in which the patient is treated, and how his or her treatment is covered by insurance, health lawyers should expect that counseling their clients will involve understanding the complex intersection of law, policy, and science related to HAIs.

CDC studies HAI science and policy and supports programs that work with federal partners, state health agencies, facilities, providers, and individuals toward reducing the burden of HAIs. In 2010, CDC and its partners in the field of infection control proposed a call to action in both the *American Journal of Infection Control* and *Infection Control and Hospital Epidemiology*, charging healthcare providers to eliminate HAIs[5] through increasing adherence to evidence-based guidelines.[6] Scientists in CDC's Division of Healthcare Quality Promotion (DHQP) in the National Center for Emerging and Zoonotic Infectious Diseases have shown that HAIs are preventable, even eliminable, when using best practices in infection control and seeking strong stakeholder involvement.[7]

As scientific understanding has evolved, the public also has come to perceive HAIs as an unacceptable problem that can be prevented and eliminated.[8] Patient advocates, healthcare providers, and facilities agree that comprehensive public health programs are necessary to eliminate HAIs.[9] Public policies that serve to reduce HAIs have evolved from those voluntarily adopted by facilities to meet national accreditation standards and receive federal reimbursements to those embedded in state and federal law. These laws impact the responsibilities of providers and facilities and thereby influence the advice health lawyers provide them.

Congress specifically directed attention to the growing burden of HAIs through the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordable Care Act of 2010, which funded states to devote employee time and resources to target HAI elimination.[10] State health agencies play a central role in preventing HAI and protecting patients across the healthcare system and serve as an important bridge between healthcare and the community.[11] For example, Tennessee's state health department recorded a 30% drop in infection rates from 2008 to 2010 after the implementation of a state HAI law authorizing the department to access facility-specific data on HAI incidence and report that data to the public.[12] In this way, current policies can support state health agency functions to collect and validate data on infections, inspect and regulate facilities, and implement improvement programs.[13]

Important Considerations for Health Lawyers

Health lawyers, their clients, and other stakeholders in HAI prevention efforts may find it beneficial to understand the scope and function of HAI laws, including developments at the federal level and in other states, for three main reasons.

First, federal reporting dynamics are changing. The purposes of CDC's National Healthcare Safety Network (NHSN), the gold standard for reporting HAI surveillance data to which over 9,000 U.S. healthcare facilities subscribe, include providing data to healthcare facilities and states for surveillance and prevention and facilitating federal reimbursement through the Centers for Medicare & Medicaid Services (CMS) Hospital Inpatient Quality Reporting Program.[14] Facilities that avail themselves of pay-for-reporting incentives by using NHSN anticipate that data will be publicly reported through CMS' Hospital Compare tool.[15] Further, state open records laws may allow the public to obtain HAI data that identifies providers or institutions when a state agency obtains NHSN data through a data use agreement with CDC or directly from facilities.[16] Where state laws mandate the use of NHSN, facilities may revisit their agreements to share identifi-

able data with NHSN.[17] Health lawyers should be prepared to advise their clients on federal incentives that impact their clients' HAI prevention activities.

Second, state laws addressing HAIs are maturing into their second or third versions in 2012. Since 2004, 33 states have passed HAI legislation, of which half have since been amended.[18] The reporting of HAIs in healthcare facilities to the public is the bedrock of these laws. Public reporting of HAI incidence can be a highly effective tool to bring down HAI rates by promoting cultural change in leadership and fostering competition and ensuring compliance with best practices among facilities.[19] However, healthcare providers, healthcare facilities, and patient advocates may seek to provide input to policy-makers and can contribute to creating the requirements to which they could later be bound. As laws change, healthcare clients will depend on lawyers for advice regarding the newest iterations of and innovations in state public reporting provisions.

Third, the nature of policy-making regarding HAIs encourages participation from both the healthcare industry and the public to more effectively bring attention and resources to the problem and new solutions.[20] Infection prevention collaboratives, many initiated through federal funding, have invited facilities and healthcare professionals to work together toward achieving HAI reductions.[21] As some collaboratives enter their final year of federal support,[22] those involved may seek state or local support or guidance in continuing their functions. Health lawyers should be prepared to advise their clients on extending collaboratives using methods that make sense fiscally and practically for individuals and institutions.

For these reasons, it is an opportune time for health lawyers to develop an understanding of the science, policy, and potential issues surrounding HAI elimination so they can better advise their healthcare clients. To this end, the CDC Office for State, Tribal, Local and Territorial Support's Public Health Law Program (PHLP) can assist health lawyers and their clients who are interested in learning about state HAI laws. PHLP's mission is to provide information to CDC and partners in state, tribal, local, and territorial jurisdictions to improve the use and understanding of law as a public health tool.

Summary of Tools and Resources

PHLP has collaborated with DHQP science and policy experts, national organizations, state governments, and other stakeholders in developing resources to describe the landscape of HAI laws. PHLP attorneys have contributed to publications describing state HAI authorities and policies with partners in CDC and the public sector, and have engaged in directed conversations with state policy and program offices. Through these endeavors, PHLP maintains tools and information that will help health lawyers understand the scope and function of state HAI laws. The following are examples of these resources:

Health lawyers representing all manner of professionals, facilities, and interest groups will need to recognize the importance of understanding HAIs and the impact that state and federal policies may have on HAI elimination.

1. A HAI policy toolkit published jointly by CDC and the Association of State and Territorial Health Officials (ASTHO) provides guidance to policy-makers on promising ways to use policy interventions to implement a comprehensive HAI prevention program.[23] The toolkit assesses the landscape of state policies to advance HAI prevention and describes mandatory public reporting, advisory councils, financial incentives and disincentives, and licensure and training requirements. To inform development of the toolkit, ASTHO assembled an expert working group of HAI prevention leaders from across the nation, including state health agency staff, legislative liaisons, legal counsel, infection preventionists, epidemiologists, and consumer advocates.

2. A HAI stakeholder engagement report published jointly by CDC and ASTHO describes the views of a broad group of stakeholders interviewed in seven states and convened in three state meetings on the provisions and effects of HAI laws.[24] The stakeholders represented state and local health agencies, consumer and patient groups, quality improvement organizations, hospitals and hospital associations, outpatient settings, healthcare professionals, and healthcare payors. Themes discussed included stakeholder confidence in policy effectiveness, contributing factors to policy effectiveness, recommended policy changes, and best options for a priority list of indicators for assessing state-level progress.

3. A menu of selected statuary provisions related to HAIs accompanies the toolkit and provides useful examples of major policy topics for attorneys drafting HAI laws, relying primarily on provisions in states with long-standing HAI programs.

4. Evaluations of impact and implementation of HAI laws are ongoing. Following an initial evaluation of stakeholders in 2011 (referenced in the report above), the next phase of work in 2012 evaluates the implementation of HAI laws by state health departments in order to understand what provisions are needed to sustain state HAI prevention programs across the spectrum of care.

5. Technical assistance is provided to state and local jurisdictions and legal support is provided to scientists, policy experts, public health practitioners, and attorneys who work to advance HAI and public health goals around the country.

6. Online and print documents and presentations that describe public health law and policy for healthcare and public health practitioners are available.[25]

For more information on any of these resources or additional links to public health law resources, health lawyers may contact PHLP at (404) 498-0470 or email the authors directly at tramanathan@cdc.gov or mpenn@cdc.gov.[26] For information on other, non-legal issues related to HAI prevention, readers may contact Elizabeth Skillen, Ph.D. Associate Director for Policy in DHQP at (404) 639-4000 or eskillen@cdc.gov.

About the Authors

Tara Ramanathan (tramanathan@cdc.gov) is a legal fellow in and **Matthew Penn** (mpenn@cdc.gov) is the Director of the Public Health Law Program in the Office for State, Tribal, Local and Territorial Support at the Centers for Disease Control and Prevention in Atlanta, GA. They have served as part of a team of lawyers and scientists who contribute to CDC's HAI prevention efforts since 2010. The authors would like to thank Montrece Ransom, JD, MPH, Senior Public Health Analyst in the Public Health Law Program, for her expert guidance in publishing and editing this piece. The authors would also like to acknowledge Elizabeth Skillen, PhD, for her invaluable contributions to the content of this piece and daily efforts to promote effective HAI prevention practices in states.

The findings and conclusions in this article are those of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention. This article should not be construed as providing legal guidance or advice.

Endnotes

1 www.cdc.gov/HAI/burden.html.
2 www.cdc.gov/HAI/infectionTypes.html.
3 R. Douglas Scott II, *The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention* (March 2009), *available at* www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf.
4 The Association for State and Territorial Health Officials, Eliminating Healthcare-Associated Infections: State Policy Options 5 (2011) (hereinafter Toolkit), *available at* www.cdc.gov/hai/pdfs/toolkits/toolkit-HAI-POLICY-FINAL_01-2012.pdf.
5 Elimination in the paper, defined in the same way as for other infectious diseases, refers to the reduction of incidence of infection maximally, through deliberate efforts and continuing measures, rather than the eradication of disease.
6 Denise Cardo et al., *Moving Toward Elimination of Healthcare-Associated Infections: A Call to Action*, Infection Control Hospital Epidemiology, Oct. 7, 2010, at 1101, *available at* www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/AJIC_Elimin.pdf (referring to the four pillars of HAI elimination as requiring the adherence to evidence-based practices, the alignment of incentives, innovation through basic, translational, and epidemiological research, and data to target prevention efforts and measure progress).
7 *Id.*
8 *See, e.g.*, Dr. Sanjay Gupta, *Alarm About Hospital Germs*, CNN.com, *available at* http://archives.cnn.com/2002/HEALTH/07/22/gupta.germs.hiv.otsc/index.html.
9 *See, e.g.*, Consumers Union, *Consumer Reports Poll Finds High Levels of Concern About Medical Harm & Support for Public Ratings on Hospital Safety*, March 31, 2011, http://safepatientproject.org/press_release/consumer_reports_poll_finds_high_levels_of_concern_about_medical_harm__support_for_public_ratings_on_hospital_safety.
10 *See, e.g.*, www.cdc.gov/HAI/recoveryact/stateResources/stateResources.html.
11 The Association for State and Territorial Health Officials, Policies for Eliminating Healthcare-Associated Infections: Lessons Learned from State Stakeholder Engagement 7 (2011) (hereinafter Summary), *available at* www.cdc.gov/hai/pdfs/toolkits/HAI-policy-case-studies-lesssons-learned.PDF.
12 *See* Tenn. Code Ann. § 68-11-263 (2006).
13 Summary, *supra* note 11, at 1.
14 NHSN Purposes, Eligibility Criteria, Assurance of Confidentiality, and Consent Agreement, *available at* www.cdc.gov/nhsn/PDFs/PurposesEligibilityRequirementsConfidentiality.pdf.
15 www.cdc.gov/nhsn/cms-welcome.html.
16 www.cdc.gov/HAI/surveillance/DUA-announcment.html.
17 *Id.*
18 *See, e.g.*, Ark. Code Ann. § 20-9-1204(e) (West 2011); Cal. Health & Safety Code § 1288.8(c) (West 2006); Colo. Rev. Stat. Ann. § 25-3-602(5)(b) (West 2006); Conn. Gen. Stat. Ann. § 19a-490n (West 2006); 16 Del. Code Ann. tit. 16, § 1003A (2007); 210 Ill. Comp. Stat. 86/25(a) (2004); Md. Code Ann., Health-Gen. § 19-134(e) (West 2006); Mass. Gen. Laws ch. 111, § 51H(b) (2008); Nev. Rev. Stat. Ann. § 439.847(1) (West 2009); N.Y. Pub. Health Law § 2819(2)(c) (McKinney 2005); 2007 Or. Laws, Ch. 838, §1; R.I. Gen. Laws § 23-17.17-9(e) (2008); S.C. Code Ann. § 44-7-2430 (2006); Tex. Health & Safety Code Ann. § 98.101(a) (Vernon 2007); Vt. Stat. Ann. tit. 18, § 9405(b)(a)(3) (2007); and Wash. Rev. Code Ann. § 43.70.056(3) (West 2007).
19 *See, e.g.*, Summary, *supra* note 11, at 7.
20 Cardo et al., *supra* note 6, at 1105.
21 www.cdc.gov/hai/recoveryact/stateResources/collaborationPrimer.html.
22 *See, e.g.*, https://www.cfda.gov/?s=program&mode=form&tab=step1&id=c3a953c68f89e07925059dd34ce65cdd.
23 Toolkit, *supra* note 4, at 1.
24 Summary, *supra* note 11, at 1.
25 *See, e.g.*, Public Health Law 101, *available at* www2a.cdc.gov/phlp/phl101/.
26 The Public Health Law Program also may be contacted at 4770 Buford Hwy. N.E., MS E-70, Atlanta, GA 30341. Fax: (404) 498-6882. Web: www.cdc.gov/phlp. The Division of Healthcare Quality Promotion may be contacted at 1600 Clifton Road, Atlanta, GA 30039. Fax: (404) 639-4043. Web: www.cdc.gov/HAI/index.html.