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Law as a tool to promote healthcare safety

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Abstract

Purpose—The purpose of this paper is to inform healthcare providers and healthcare facility leadership about the statutory, administrative, criminal, and tort law implications related to preventable harms from unsafe injection practices.

Design/methodology/approach—Review of legal theory and precedents.

Findings—The law can address disputes over unsafe injection practices in a variety of ways. Administrative agencies may hold a provider or facility responsible for preventable harms according to specific statutory and regulatory provisions governing licensure. State courts can compensate victims of certain actions or inactions based on tort law, where a breach of a legal duty caused damages. Prosecutors and the public can turn to criminal law to punish defendants and deter future actions that result in disability or death.

Research limitations/implications—The state law findings in this review are limited to legal provisions and court cases that are available on searchable databases. Due to the nature of this topic, many cases are settled out of court, and those records are sealed from the public and not available for review.

Practical implications—Preventable harm continues to occur from unsafe injection practices. These practices pose a significant risk of disease or even death for patients and could result in legal repercussions for healthcare providers and facility leadership.

Originality/value—This article reviews emerging law and potential legal implications for health care and public health related to unsafe medical practices related to needle, syringe, and vial use.

Keywords

Quality; Health policy; Safety culture; Adverse incidents and hospital acquired infection; Environment of clinical practice; Patient litigation

Introduction

Infection and injury due to unsafe injection practices in healthcare settings are considered preventable harms, and as such, may provide grounds for legal disputes. The law can be a deterrent and thereby a tool for prevention, providing options to prosecutors and the public

under existing legal sources. This article provides an overview of the principles of which readers should be aware when considering potential legal impact of preventable harms on providers and facilities. In particular, the article covers public health law, legal responses to preventable harms, and uses of the law as a tool for prevention.

Injection safety and, more broadly, unsafe practices related to needle, syringe, and medication vial use remains a vitally important issue to today's healthcare and public health fields. Although public health interventions are designed to improve provider practices, preventable harms related to unsafe practices occur through numerous procedures and in a variety of settings. Researchers estimate that unsafe injection practices resulted in the notification of potential exposure to infections over 130,000 patients in the US from 2001 to 2011 (Guh *et al*., 2012).

The harms resulting from unsafe injection practices are preventable. The US Centers for Disease Control and Prevention (CDC) is a source of evidence-based guidelines for safe injection practices in all healthcare settings (Siegel *et al*., 2007). Provider and patient education campaigns conducted in partnership with state health departments support the single use of needles and syringes and have influenced best practices and policies. Patient safety advocates also call for transparency in the information disseminated about the preventable harm histories of providers and facilities. Although attention and resources have been devoted to injection safety for years, reports of unsafe practices continue to surface as the scope of practice for facilities and providers change in response to healthcare advances and financial incentives.

Legal framework for supporting public health goals

The public health and patient safety goals promoted by the evolving legal framework in the USA have significant consequences for healthcare providers and facilities. This framework consists of statutes, regulations, and case law that affect the responsibilities of public health and healthcare practitioners to address unsafe practices that result in preventable harms.

The Supreme Court has long upheld the authority of states and localities to promote public health goals by enforcing their police powers, specifically empowering state agencies to regulate the behaviors and activities of private entities and the public (*Jacobsen* v. *Massachusetts*, 1905). Many public health responsibilities dictated in state statutes and regulations therefore sit with state and local health-related boards and agencies, some of which regulate healthcare facilities and providers. Agencies may promote best practices, license health professionals and facilities, and levy fines or report criminal conduct for certain actions or inactions (Gostin, 2000). Healthcare facility leadership and providers should be aware of the institutional and individual requirements imposed by the legal framework.

Law enables public and private institutions to promote public health and safety objectives. Statutes that empower state health agencies to establish regulatory provisions may concurrently enable healthcare entities to support disease prevention. Health professional boards in states may determine whether professionals are fit to practice and sanction providers for breaches of licensure requirements (Cal. Bus. and Prof. Code § 3529, 2013).

Regulations promulgated by state health agencies could hold healthcare facilities responsible for certain adverse health outcomes and facilities could require individual healthcare providers to meet specific standards or observe certain conduct through institutional policies or employment contracts (25 Tex. Admin. Code § 134.47, 2004). In addition to the statutory and regulatory requirements, third parties such as professional organizations and federal entities may incentivize certain activities or behaviors through standards, certifications, and monetary incentives and penalties (Centers for Medicare and Medicaid Services, 2013).

Laws also delegate authorities and responsibilities to individuals to support public health and safety goals. State public health regulations seek to improve access to health care by establishing, for example, a broad scope of practice for rural providers who meet enhanced training requirements (Ariz. Rev. Stat. § 32-3106, 1985). Certain healthcare providers with regulatory responsibilities may face civil liability for their actions and the actions of those they employ (*Parker* v. *Freilich*, 2002). In many states, the law may penalize nurses for their actions or inactions based on a professional standard of care (*Farmer* v. *Willis-Knighton Medical Center*, 2013); require physicians to report employees' errors (28 Pa. Code § 27.6, 2002); and hold pharmacists accountable for the actions of those they train for practice (S.C. Code § 40-43-86, 2009). Laws mandate or prohibit certain activities for professionals or facilities through licensure standards. Legal provisions may incorporate certain professional or independent resources by reference into their requirements, such as communicable disease prevention protocols and patient notification recommendations from CDC (Wash. Admin. Code § 246-330-176, 2009; Alaska Stat. § 47.05.012, 2012). Federal and state laws can provide strong incentives for compliance with best practices, including reimbursements through Medicare and Medicaid.

In addition to understanding the legal framework that supports public health goals, legal mechanisms that address public health problems may impact healthcare facilities and providers. Laws recognize, evaluate, and determine the consequences for unsafe practices that result in preventable harms in a variety of ways.

Legal mechanisms for addressing preventable harms

Where unsafe practices compromise public health goals, healthcare facilities, and providers may be responsible for addressing any resulting harms. Laws determine whether breaches in patient safety can have legal consequences for individuals and institutions. Healthcare and public health practitioners may need to become aware of the legal mechanisms available for addressing preventable harms.

Laws do not address preventable harms and adverse events uniformly. Federal regulations define "adverse events" for the purposes of providing incentives and disincentives; accordingly, some healthcare decisions that result in negative outcomes are explicitly excluded from reimbursement by Medicare (Wachter *et al*., 2008). Some state laws recognize and define a preventable harm and require health officials to develop guidance on best practices (N.Y. Pub. Health Law § 239-a, 2008; New York State Department of Health, 2013). For example, a reused syringe or needle that results in a healthcare-associated infection could trigger reporting mechanisms and sanctions for a provider (N.Y. Pub. Health

Law § 2819, 2006). Other states do not specify the event or the resulting harm, and instead incorporate Joint Commission and other third-party definitions by reference into state codes. Laws either recognize external standards and guidelines from a particular edition or year or allowing for the automatic incorporation of their revisions (Alaska Admin. Code tit. 7, 27.010, 2006).

Despite this varied nomenclature, responses to preventable harms take well-trodden paths. State public health law, criminal law, and tort law play discrete and specific roles in upholding public health goals, providing incentives, and establishing consequences. Public health law, through administrative actions, is used to establish a system of responsibility and promote prevention. Criminal law is used to punish and deter defendants, whereas tort law is used to compensate victims. Governmental bodies use these mechanisms individually or in combination to respond to patient safety events.

Legal responses to preventable harms: administrative actions

State public health laws allow the government to hold a provider or facility responsible for preventable harms and promoting best practices. States use their police powers, recognized under the 10th Amendment to the US Constitution, to grant executive agencies the authority to sanction and penalize those they regulate. Statutes and agency regulations permit health officials to fine providers and facilities, professional boards to suspend or revoke licenses of providers, and law enforcement officials to close down facilities and arrest providers. Public health laws also can be instrumental in incentivizing and enforcing best practices through statutory or regulatory standards for providers and facilities in a state or locality (Gostin, 2000).

State laws can impose responsibilities on individuals and some healthcare entities through licensure provisions. Each state allows providers to practice if they comply with initial educational and safety requirements. Similarly, laws authorize certain kinds of facilities to treat patients if they show regular compliance with regulations and meet periodic certification requirements in order to maintain licensure. States can incentivize prevention activities through licensure regulations, typically requiring facilities to report infections or other conditions within specified time frames and personnel to become trained or certified at regular intervals. States can also disincentivize noncompliance, and individuals could face criminal penalties for operating without a license. Some types of healthcare facilities and providers must undergo inspection by regulatory officials and share certain patient data with public health officials under certain conditions, sometimes even without patient consent, when required for licensure (N.C. Gen. Stat. Ann. § 131D-2.11, 2011; Wis. Admin. Code DHS § 127.05, 1999).

Under some state regulations, patients who experience preventable harms may be able to report providers or facilities to a regulatory agency. These provisions allow the state to pursue administrative penalties through the agency or licensure sanctions through professional boards to penalize facilities and providers, respectively. When a patient receives care under the auspices of the state through public health insurance or service delivery, the patient may appear before a state agency and pursue compensation through its administrative court (*Hawkins* v. *Community Health Choice, Inc*., 2004). Although the state

may compensate the patient, the decision does not necessarily affect future decisions for other plaintiffs based on the same preventable harm or actions or inaction by the same providers and facilities (*Mesbahi* v. *Maryland State Bd. of Physicians*, 2011).

Legal responses to preventable harms: criminal law

States can deter unsafe practices through criminal laws that authorize fines and jail sentences. Criminal penalties vary significantly between jurisdictions and often depend on the intent and severity of a crime. Crimes are defined by severity in statutes and ordinances that cover certain behaviors and actions and may include a reference to a person's intent. Where an action rises to the legal standard described in a criminal statute, a state or local prosecutor can bring charges against an individual provider, or defendant, who has the requisite intent for the charge. For example, a provider whose failure to use safe injection practices results in a patient's death could be charged with manslaughter if the prosecutor can show that the provider's intent rose to the level of criminal negligence, which does not relate to civil negligence standards (*Hampton* v. *State*, 1905). The prosecutor has the burden of proof to show that a defendant violated the criminal standard “beyond a reasonable doubt,” although certain incriminating actions could heighten a charge and mitigating factors could lessen a charge.

While constitutional principles forbid a single defendant to be charged twice for a single crime, multiple defendants may be found guilty for the same crime. In the case of preventable harms, providers or others complicit in knowledge, intent, or action or inaction of a principal provider may be culpable for the resulting crime through accomplice liability. Accomplices may be charged independently of the principal, and could be punished even when the principal has not been convicted or has been acquitted (Ind. Code § 35-41-2-4, 1976). A healthcare entity or institution may not face criminal liability for death or disability of patients (though may for financial losses), but organizational actors such as employers or supervisors could face punishment upon meeting the specific requirements of intent for accomplice liability (*Com* v. *Life Care Centers of America, Inc*., 2010).

Criminal laws are used to punish a defendant on behalf of the state and the public and deter future criminal behavior. Because criminal charges do not compensate victims of preventable harms, those individuals may have to pursue an action in civil court for damages. The same criminal defendant can become a civil defendant simultaneously, and a state or federal court must apply completely different legal standards for finding an injury and compensating a plaintiff patient.

Legal responses to preventable harms: tort law

Tort law seeks to compensate victims of certain actions or inactions based on the breach of a legal duty that caused damages. Plaintiff patients seeking redress for a preventable harm can file a tort, or personal injury, suit in state or federal court and must establish that the defendant's action met the standards for the criteria of duty, breach, causation, and damages. The defendant provider or facility then may present evidence to defend the suit and show that these four requirements were not met.

In tort law, providers and facilities connected to a preventable harm can be named in a suit as defendants based on their respective roles and duties; accordingly, employers may be vicariously liable for employees' actions, corporate entities can be held liable for their affiliated facilities, and providers can be jointly and severally liable for actions for which they each held responsibility (*Insco* v. *Aetna Health and Life Ins. Co*., 2009). State courts use case law decisions that penalize defendants and compensate plaintiffs to uphold "private rights of action." These decisions could have consequences for future plaintiffs with the same complaints.

For healthcare providers and facilities sued based on the failure to meet a certain "standard of care," the legal standard of care does not equate directly to a medical standard of care. The legal standard simply asks that a provider follow the same course as a reasonable provider would under the same circumstances: there are no technical requirements as in a medical standard of care (Moffett and Moore, 2011). A jury that finds that the requirements for a tort suit are met will find the defendant liable for the plaintiff's damages. These damages may be considered "compensatory," reflecting the monetizable damages sustained, or "punitive," scaled to effectively penalize the defendant.

Courts may require providers and facilities to pay compensatory and punitive damages to plaintiff patients as a way to address the harms they experienced. Some contracts that patients and providers sign for healthcare delivery may require patients to seek compensation for injuries through negotiation or arbitration before seeking redress in court, but a judge may also recommend that plaintiffs and defendants reach an out-of-court settlement without facing a jury trial. Because the records of arbitrated and settled disputes are not usually made available to the public, the depth and breadth of injury and compensation across suits related to preventable harms are difficult to gauge.

Legal responses to preventable harms: injection safety events as examples for legal action

Preventable harms have been addressed in the past by licensure boards, administrative law judges, and state courts. Healthcare practitioners should be aware of legal actions brought in the states in which they practice, but several foundational cases related to injection safety events directly exemplify the principles discussed in this review and remain standards for new cases brought today.

A pair of cases from New Jersey from 1963 show the simultaneous criminal prosecution and licensure action against a physician who was convicted on 12 counts of involuntary manslaughter for the infection and resulting death of 12 patients with hepatitis B. The state supreme court took the case on appeal and decided that the prosecution did not establish a causal connection "by expert proof" between the deaths and a specific act or omission of the physician, or even identify all of the acts of omissions which could have caused the disease to be transmitted (*State* v. *Weiner*, 1963). The criminal prosecution eventually was reversed on appeal and the charges dropped due to insufficient causation, so the licensure revocation "based on crimes of moral turpitude" was also reversed (*State Bd. of Medical Examiners* v. *Weiner*, 1963).

A series of civil negligence cases brought for actions related to a hepatitis C outbreak in New York provides an example where the full range of legal actions was available to try a physician and facility leadership (*Von Stackelberg* v. *Goldweber*, 2011; *Bernard* v. *Goldweber*, 2012; *Doe* v. *Goldweber*, 2013). The New York City Department of Health and Mental Hygiene found a number of probable outbreak-associated cases of hepatitis B and C among patients who had received injections from medication vials from a single physician between 2003 and 2007. Concurrent with the outbreak investigation, the state Office of Professional Medical Conduct suspended and later revoked the physician's medical license, charging him with “gross incompetence, gross negligence, and failure to comply with provisions governing the practice of medicine, as a result of his violation of infection control practices and for allowing his infection control certification to lapse.” While the physician filed bankruptcy, plaintiffs, some deceased, sued the group practices that retained him to provide services in several ambulatory surgery centers. Because the failure to investigate the physician's licensure and supervise and monitor his actions did not rise to vicarious liability, willful behavior, or negligent hiring by the group practice physicians, complaints against them were dismissed.

The New Jersey State Board of Medical Examiners petitioned the Supreme Court of New Jersey to review its authority to sanction a physician who caused 92 counts of hepatitis C. The Board sought to levy administrative penalties on the physician after revoking his license to practice (*Matter of DeMarco*, 1980). The court allowed the Board to interpret the civil strict liability of the physician for statutory violations to impose multiple penalties upon finding multiple violations. A civil case brought against the same physician by a patient also sued his out-of-state medical malpractice insurer in the same complaint for indemnification of his claims (*DeMarco* v. *Stoddard*, 2014). The insurer had previously rescinded the physician's malpractice policy, and a prior court judgment against the physician voided the policy, but the court required the insurer to indemnify the patient and awarded the patient attorney's fees.

Because these cases are based on the law of the states in which they were brought, their decisions are not applicable to every jurisdiction. In addition, the procedural history and factual issues in each case greatly impacted the outcome for each patient, provider, and facility implicated. Healthcare providers and facility leadership should consult counsel licensed in their state of operation about similar cases involving licensure, liability, and related legal concerns.

Legal action as a tool for prevention

The use of law as a tool to address preventable harms and promote health in states through incentives, disincentives, and deterrence also can support disease prevention. Public health law also plays a role in preventing negligent practice.

State statutes and regulations can follow the latest trends and information in public health. For example, Nevada and North Carolina, guided by public health principles, recently promulgated state regulations that expressly promote injection safety. Following the conviction of a Michigan physician who reused needles, sutures, and other instruments for

fraud, patient advocacy resulted in the passage of state legislation that prohibits the reuse of medical devices designed for single use with criminal and administrative penalties (Mich. Comp. Laws. Ann. § 333.20153, 2010).

Courts may allow patients to seek relief from a variety of parties in order to best assign responsibility for an injection safety episode. For example, in a Nevada outbreak of hepatitis C from an endoscopy clinic, plaintiffs have sued the physician involved, his clinic manager, a nurse anesthetist, and even the pharmaceutical corporation that manufactured the anesthetic in question (*Grosshans* v. *Endoscopy Center of Southern Nevada*, 2011; *Sicor, Inc*. v. *Hutchison*, 2011). The physician also faced criminal charges of second degree felony murder, and was convicted and sentenced to life in prison (*Desai* v. *Nevada*, 2013; German, 2013). Public reaction to the outbreak resulted in changes to Nevada laws and regulations to prevent future incidents and patient harm.

By providing resources to the public and allocating responsibility to the full roster of actors, law can promote better injection safety practices going forward. Changes to law and policy that seek to improve healthcare delivery may impose additional requirements on healthcare providers and facility leadership while also requiring attention from state and local health and regulatory officials. Although each state's provisions are unique, law serves as a tool to promote public health and prevention throughout the nation.

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Appendix. Cases

- *Bernard* v. *Goldweber*, 34 Misc.3d 1223(A) (2012).
- *Com* v. *Life Care Centers of America, Inc*., 456 Mass. 826, 926 N.E.2d 206 (2010).
- *DeMarco* v. *Stoddard*, 2014 WL 237823 (Jan. 22, 2014).
- *Desai v. Nevada*, 2013 WL 1092451 (Mar. 13, 2013) (unpublished order denying a petition for writ of habeas corpus challenging the charges of murder).
- *Doe* v. *Goldweber*, 112 A.D.3d 446 (2013).
- *Farmer* v. *Willis-Knighton Medical Center*, 109 So. 3d 15 (2013) (holding that nurse breached standard of care by injecting potassium intravenously).
- *Grosshans* v. *Endoscopy Center of Southern Nevada*, 2011 WL 4448940 (Sept. 23, 2011) (naming the facility, the physicians, nurse practitioners, nurses, and healthcare product manufacturers implicated in the outbreak).

- *Hampton* v. *State*, 50 Fla. 55 (1905) (stating that indicators of criminal negligence in a patient safety case may include instances where a provider "exhibits gross lack of competency, gross inattention, or criminal indifference to the patient's safety).
- *Hawkins* v. *Community Health Choice, Inc*., 127 S.W.3d 322, 325 (2004).
- *Insco* v. *Aetna Health & Life Ins. Co*., 673 F.Supp.2d 1180 (2009) (denying an insurer's motion to dismiss for a negligence claim by an insured for contracting hepatitis C).
- *Jacobsen* v. *Commonwealth of Mass*., 197 U.S. 11 (1905).
- *Matter of DeMarco*, 83 N.J. 25 (1980).
- *Mesbahi* v. *Maryland State Bd. of Physicians*, 201 Md. App. 31529 A.3d 679, 688-9 (2011) (holding that agencies do not need to strictly follow precedent, although they frequently use prior decisions as standards for other cases).
- *Parker* v. *Freilich*, 803 A.2d 738 (2002) (holding that doctors may be liable for the performance of their independent contractors with ostensible agency).
- *Sicor, Inc*. v. *Hutchison*, 266 P.3d 608 (2011) (permitting a product's liability suit to take place in the state).
- *State Bd. of Medical Examiners* v. *Weiner*, 41 N.J. 56 (1963).
- *State* v. *Weiner*, 41 N.J. 21 (1963).
- *Von Stackelberg* v. *Goldweber*, 33 Misc. 3d 1229(A) (2011).

Biography

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