RISKS IN MEDICAL CARE, PART 6

Health Care Providers Face Complex Legal and Regulatory Risks

by Cindy King, Director of Membership Services and Human Resources

Healthcare providers must comply with an alphabet soup of federal and state agencies and 629 distinct regulatory requirements.

SAFE, HIGH-QUALITY healthcare is something everyone wants, including healthcare professionals. However, providing healthcare services comes with its own set of legal and regulatory risks.

Roles and responsibilities
Complying with standards and regulations is the shared responsibility of managers, who may or may not be licensed healthcare professionals; doctors, nurses, and other practitioners who serve patients; and individuals who manage or oversee medical equipment and facilities.

Providing legally compliant healthcare entails more than simply performing the duties outlined in one's job description. It encompasses doing the right thing—legally, ethically, and morally.

Typically, the chief compliance officer or director of compliance and regulatory affairs has primary responsibility for legal and regulatory compliance. Roles in specific areas, such as environmental compliance or clinical compliance specialist, may also exist and often require a law degree.

Regulatory agencies and laws
The American Hospital Association (AHA) notes in its *Regulatory Overload Report* published May 4, 2023: "Health systems, hospitals and PAC [post-acute care] providers must comply with 629 discrete regulatory requirements across nine domains." [1]

The report estimates that "providers [collectively] spend nearly $39 billion a year solely on the administrative activities related to regulatory compliance."

The report identifies the four agencies that set these requirements: the Centers for Medicare and Medicaid Services, (CMS), the Office of the Inspector General (OIG), the Office for Civil Rights (OCR), and the Office of the National Coordinator for Health Information Technology (ONC).

Providers are regulated by other federal and state agencies and laws, including the Americans with Disabilities Act (ADA), Health Insurance Portability and Accountability Act (HIPAA), and the Affordable Care Act (ACA).

The purpose of the Federation of State Medical Boards (FSMB) is "to protect the public from the unprofessional, improper, unlawful or incompetent practice of medicine."

According to its website, FSMB "represents 71 medical boards in the United States, its territories, and the District of Columbia. FSMB assists these boards as they go about their mandate of protecting the public's health, safety and welfare through proper licensing and discipline of physicians and, in many jurisdictions, physician assistants and other health care professionals." [2]

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1 https://www.aha.org/guidesreports/2017-11-03-regulatory-overload-report
2 https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/introduction/

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Providers must also comply with regulations on the use of medical equipment and devices under the purview of the U.S. Food and Drug Administration. Among these are regulations for personal protective equipment, diagnostic x-ray equipment, oxygen generators, laboratory practice regulations, and regulations regarding the use of drugs and antibiotics. [3]

State regulations

According to Michigan's Licensing and Regulatory Affairs, the state's Bureau of Community and Health Systems (BCHS) "performs regulatory duties as required by state and federal laws. Programs are designed to protect the health, safety, and welfare of individuals receiving care and services through various covered licensed, permitted, and certified facilities, agencies, programs, and individuals.

"The bureau oversees adult foster care facilities, adult foster care and children camps, freestanding surgical outpatient facilities, homes for the aged, hospice agencies and residences, hospitals, nursing homes, substance use disorder programs as well as certified nurse aides, nurse aide trainers, nurse aide training programs, and qualified interpreters." [4]

Consulting firm Crowe identifies some results of noncompliance with regulations, including "class-action lawsuits and significant legal, regulatory, and financial consequences. Other common results of noncompliance include fines, reputational loss, and costly corporate integrity agreements."

To avoid these risks, Crowe advises healthcare providers to "understand the federal government's focus areas relative to combating fraud, waste, and abuse, which can be accomplished through regular review of state and federal regulator websites." [5]

In its May 12, 2023 article, *Healthcare Compliance Risk Management Strategies for Effective Implementation,* [6] Net Health suggests the following strategies for maintaining a high standard of compliance:

Establish a compliance culture. Leadership should prioritize compliance and foster

Michigan's Bureau of Community and Health Systems oversees a wide range of healthcare facilities.

a culture where employees understand and value the importance of adherence to laws, regulations, and ethical standards. Regular training, clear policies, and open communication channels can help.

Conduct comprehensive risk assessments. This helps identify areas of vulnerability and potential compliance gaps. Assessments should cover all aspects of operations, including clinical processes, information systems, vendor relationships, and internal controls.

Develop detailed policies and procedures. This is the backbone of an effective compliance program. Policies should outline expectations, responsibilities, and guidelines for compliance, covering areas such as patient privacy, data security, billing and

coding, and interactions with pharmaceutical companies. Regular reviews and updates are also essential.

Implement robust training and education programs. Provide regular training to address relevant compliance topics, industry best practices, and changing regulations. Tailor education to different roles and responsibilities, ensuring that all employees have the specialized knowledge to meet requirements.

Establish monitoring and auditing mechanisms. Implement automated systems for tracking and analyzing data to identify patterns, anomalies, and potential risks. Conduct regular audits to assess adherence to policies and procedures, billing accuracy, and overall compliance.

Encourage whistleblower reporting. Create an anonymous reporting mechanism for employees to raise concerns or report potential compliance violations. This includes whistleblower protection policies and assurance that identified concerns will be taken seriously, investigated, and addressed appropriately.

Foster collaboration and partnerships. Healthcare organizations should work closely with external stakeholders such as legal counsel, compliance consultants, and industry associations. This can provide valuable insights into changing regulations, industry best practices, and emerging compliance risks.

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3 https://www.fda.gov/search?s=regulations%2C+medical+equipment
4 https://www.michigan.gov/lara/bureau-list/bchs
5 https://www.crowe.com/insights/healthcare-connection/top-risks-healthcare-organizations-2020
6 https://www.nethealth.com/blog/healthcare-compliance-risk-management-strategies/

New, Expanded Funding Opportunities in RAP and CAP Grants

EACH YEAR, WITH THE guidance of MMRMA staff, the Membership Committee reviews and updates Risk Avoidance Program (RAP) and Certification and Accreditation Program (CAP) grant guidelines.

Standard Grant Guidelines are established to provide fair and equitable funding to MMRMA members for programs designated as best practices to reduce risk. During the May 10, 2023 Membership Committee meeting, a significant number of updates were made to the Standard Grant Guidelines as summarized below.

General Updates to Program Guidelines

Supporting Documentation Requirements. Quotes and invoices from the selected vendor MUST be included with the final grant application submission to MMRMA. A clear line-item cost of the component(s) included in the grant funding request is **required**. If the line-item cost is $0, funding will not be considered.

Revisions to Standard Grant Funding

Electronic Prisoner Monitoring. Maximum funding has been increased from $5,000 to $10,000.

Two (Multi)-Factor Authentication. Maximum

Six new areas of funding were approved, including use of drones in law enforcement, in building operations, and for inspection of power lines and dams.

These changes apply to grant applications submitted during the quarterly cycle ending on July 10, 2023.

funding has been increased from $10,000 to $30,000.

Vulnerability Assessment/ Penetration Testing. Maximum funding has been increased from $10,000 to $25,000.

Automatic External Defibrillators. Funding has been expanded to include equipment for courtroom facilities. Funding was previously limited to equipment in jail or lockup facilities.

Bumper Guards. Maximum funding has been increased from $5,000 to $10,000.

Body Worn Cameras. Funding has been revised to 50% up to a maximum of $400 per unit.

In Car Cameras. Funding has been revised to 50% up to a maximum of $1,000 per unit.

Tasers. Funding has been revised to 50% up to a maximum of $500 per unit.

Non-Transport Lifting Devices and Stair Chairs. Funding has been revised to 50% up to $5,000 per unit, with maximum funding of $10,000 per member.

New Funding Opportunities

Accreditation Assistance. Funding of 50% up to a maximum of $10,000 to assist with the cost of hiring a professional service to facilitate departmental accreditation processes.

Corrections Security/Physical Improvements. Funding will provide for 50% up to $50,000 for improvements in corrections facilities.

Storage Infrastructure Security. Funding of 50% up to a maximum of $40,000 for implementation of new data backup or business continuity systems that are purposely designed to be resistant to cyber threats.

Communications Training Officer (CTO). Funding up to 50% of tuition and related expenses associated with the completion of CTO training for newly hired dispatchers.

New Certification and Accreditation Grants

Zoning Board of Appeals Online Certificate– Michigan State University Extension

Certified Protection Professional– American Society for Industrial Security (ASIS)

Physical Security Professional–ASIS

Dispatch Training. 50% of tuition and related expenses associated with general dispatch training offered by, but not limited to, organizations including NENA, APCO, PowerPhone, and Priority Dispatch.

Drones and Associated Technologies. Funding of 50% up to a maximum of $10,000 per member for drones and associated technologies used in law enforcement operations, heat loss detection from buildings, and inspection of power lines and dams.

Law Enforcement Training on Active Violence Incidents

*by Mike Berthā, Senior
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HARDLY A DAY GOES BY without news reports of another mass shooting somewhere in the United States. Long gone is anyone's sense that "it cannot happen here."

The FBI defines a "mass shooting" as any incident in which at least four people are murdered with a gun; news network CNN defines it as one in which four or more people are shot. Definitions aside, no one can deny the tragedy or sense of loss felt by families and communities when such an incident occurs.

Changing the approach to violent acts

We have witnessed how assailants engage innocent bystanders and target individuals while they move from location to location. Suspects resort to the use of lethal force quickly and demonstrate the propensity to continue to do so.

In the past, law enforcement resources were typically deployed to surround and contain threatening incidents. Police tried to make contact with assailants and determine what motivated their violent actions. However, after the Columbine High School shooting in Colorado in 1999, law enforcement began to reconsider the "surround and wait for SWAT" strategy.

Patrol units are often first to respond to lethal encounters and are responsible for locating and neutralizing the threat. Consequently, they are forced to deploy without the opportunity to rehearse or research the geographic area—practices common to specialized team deployments.

Shifting protocols and training initiatives

The increasing frequency of violent episodes has forced law enforcement agencies—including those of MMRMA members—into a position of immediate action.

Active violence training has been required training for all law enforcement officers in Michigan since January 1, 2020. The law is explicit regarding this requirement.[1] All law enforcement agencies in the state must ensure that their officers receive training vetted by the Michigan Commission on Law Enforcement Standards and are encouraged to contact MCOLES to make sure their training and trainers meet this standard.

Reality-based training

For more than a decade, MMRMA has provided its members with two-day, reality-based training on response to active violence. Officers learn a practical, systematic approach that affords maximum security when moving through a hostile environment. The course includes a history and characteristics of active shooter incidents, terminology and definitions, and tactical techniques.

Course objectives include:

> Knowing the difference between an active shooter and a barricaded gunman.

> Identifying the types of formations and responsibilities of each officer.

> Demonstrating the ability to transition from one response to another and explain why.

> Showing how to armor patrol vehicles for approaches or rescues.

> Controlling lighting to enhance safety.

> Demonstrating extraction techniques for injured persons.

> Understanding the importance of mental conditioning before and after an incident.

1 http://legislature.mi.gov/doc.aspx?mcl-28-609e