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EDITOR'S CORNER

The Risk Management Quarterly (RMQ) is the official journal of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) and is published several times a year.

RMQ's Mission Statement: To enhance the quality of healthcare delivery through education, research, professional practice, and analysis specific to risk management issues.

This journal contains articles on a wide variety of subjects related to risk management, patient safety, insurance, quality improvement, medicine, healthcare law, government regulation, as well as other relevant information of interest to risk managers. The articles are usually written by ***AHRMNY*** members, so the journal serves as an opportunity for members to showcase their writing talents.

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Article Requirements: Maximum article length 3,500 words; Photos should be high resolution JPEGs (at least 300 dpi); AHRMNY will not publish articles promoting products or services.

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The information presented in THE RISK MANAGEMENT QUARTERLY is for educational purposes only.

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SUBMIT AN ARTICLE

We are asking our readers to submit articles for future editions of the RMQ journal. We accept articles that focus on patient safety, environment or staff safety, risk management, claims management, insurance issues and other relevant topics.

The deadline for submission and consideration for the next journal is **September 30, 2017**.

Click here for author guidelines



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Membership affords opportunities to keep current of relevant risk management issues and network with other industry professionals.

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PRESIDENT'S MESSAGE

The Board of Directors would like to take this opportunity to wish everyone a wonderful summer and to thank you for your support throughout the year. We have had a very successful year and are most grateful for all the support from our generous sponsors as well. To recap a few highlights, we had our first conference on Long Island in 30 years, this past winter, that was well attended and we have already booked this venue for next year.

Our annual conference was held on June 9th at the beautiful Andaz Wall Street Hotel. We had 128 in attendance. Our keynote speaker, Greg Prentiss, Press Ganey consultant, engaged the audience with his talk on High Reliability in Healthcare. He captivated us with his video of a landing onto an aircraft carrier.

The breakout sessions in the am included "Managing Adversity with Diversity, Managing Distinctive Personality Types in the Behavioral Health and Aging Services Environment, Prosecuting Elder Abuse and lastly Emerging Trends in Medical Malpractice.

We had an informative and excellent Panel discussion on ERM, which was hosted by Mike Midgley, ASHRM President, Barbara McCarthy, ASHRM Past President and our very own Dr. Victor Klein, also an ASHRM board member.

Thank you to the to the education committee for putting together an excellent program and our hard working fundraising committee who assisted us in supporting our event.

I truly feel honored to serve as the President of this terrific organization. We are committed to being the New York central source of information and leader in healthcare risk management and patient safety.

We encourage all of you to get involved and promise it will be a rewarding experience. Please consider volunteering to work on one of our various committees.

Stay tuned for information about upcoming educational programs.

Best regards,

Lesli Giglio, President
July 1, 2017-June 30, 2018

Criminal Conduct in Hospitals: Is the Hospital Liable?

By Sean B. Maraynes, Esq.

Hospitals are commonly named as defendants in medical malpractice lawsuits for claims arising from injuries alleged to have occurred on their premises. However, in addition to claims related to care rendered by health care practitioners, hospitals are faced with lawsuits when a crime is committed by a hospital employee or a third party on hospital premises. Given the salacious nature of a sexual or physical assault, when such incidents do occur, plaintiffs' attorneys will attempt to bring the hospital into the case to access its "deep pockets." The following examines common legal theories, best practices to avoid such claims and, if necessary, how to defend against them.

Criminal Conduct Scenarios

Sexual assaults by health care practitioners were brought to the forefront in September 2016 when the *Atlanta Journal-Constitution* released a five-part investigative series examining the alleged epidemic of physician sex abuse in all 50 states. Claims of sexual abuse, either substantiated or unsubstantiated, frequently involve a patient rendered unconscious by anesthesia or a female patient left alone with a male health care provider during an examination or procedure. In addition to allegations of sexual assaults, hospitals are faced with claims of physical assaults that occur within their walls. Physical assaults can involve a worker who becomes violent with a patient, an emotionally disturbed patient who attacks another patient or even employee-on-employee workplace violence.

In nearly all scenarios involving a sexual or physical assault by an employee, the alleged criminal act is *ultra vires*, meaning it falls outside the scope of the employee's duties. Therefore, the doctrine of *respondeat superior* does not apply and the hospital cannot be held vicariously liable as the employer. Because vicarious liability for an employee's conduct is not an available avenue, plaintiffs will commonly bring lawsuits under a theory of negligent hiring, supervision or retention, or allege independent negligence on the part of the hospital that resulted in the tortious or criminal act.

Theory of Negligent Hiring, Supervision or Retention

In New York, a claim for negligent hiring, supervision or retention arises when an employer places an employee in a position to cause foreseeable harm that the injured party most likely would have been spared had the employer taken reasonable care in supervising or choosing whether to retain the employee.

Clearly, if an employee has a history of sexual or other violent misconduct that the employer either knew about or could have learned about with a reasonable background check, there is potential exposure. Additionally, if the employment file does not contain well-documented periodic evaluations, a plaintiff's attorney can argue the employee was not properly monitored for misconduct.

Given the elements of a claim for negligent hiring, supervision or retention, the critical issue often will be whether the employee's conduct was foreseeable. Plaintiffs' attorneys will attempt to obtain and use any scintilla of evidence that could demonstrate that the employee's criminal conduct was foreseeable. In this digital age, plaintiffs' attorneys have access to a potential wealth of incriminating evidence. In addition to employment files, prior complaints and government investigations, plaintiffs' attorneys will seek discovery of work emails, digital messages contained on work cellular telephones and even social networking websites in an attempt to demonstrate the employee had a tendency to engage in misconduct.

Despite the potential for more incriminating evidence, it has been very difficult historically for plaintiffs to prevail on a claim of negligent hiring, supervision or retention against the hospital. The New York Official Reports have many appellate level decisions affirming the dismissal of claims against hospitals involving a hospital employee who was accused of sexual misconduct because there was no evidence in the record from which a juror could reasonably infer a known propensity toward sexual misconduct.

Theory of Independent Negligence

A more promising tactic for plaintiffs' attorneys is to develop an independent theory of negligence against the hospital. Like other property owners, "A hospital also has a special duty to safeguard the welfare of its patients, even from harm inflicted by third persons, measured by the capacity of the patient to provide for his or her own safety."

A common theory of independent negligence is that the hospital (employer) failed to promulgate appropriate policies to prevent sexual misconduct. For instance, a plaintiff may claim the hospital failed to have a proper chaperone policy in place for female patients during the performance of procedures involving an intimate area of the body. Whether this type of allegation is defensible may require an expert review in the medical specialty to support the claim that provision of a chaperone is not a customary or required medical practice.

With regard to hospital liability for the criminal conduct of third parties, one of the more frequently brought claims accrues when a psychiatric patient known to be dangerous is not properly supervised during admission to the hospital. Defending and, more importantly, preventing this type of claim will require prompt assessments of patients who are emotionally disturbed in addition to fluid communication with a well-staffed hospital security department trained to monitor and, if necessary, remove such dangerous patients.

In sum, although plaintiffs' attorneys face an uphill battle when asserting claims against hospitals arising from sexual or physical assaults, a hospital may leave itself open to a high-exposure claim unless it can demonstrate well-documented background checks, well-documented periodic evaluations, thoughtful chaperone policies and a well-trained security department.

ABOUT THE AUTHOR



Sean Maraynes is an associate in Wilson Elser Moskowitz Edelman & Dicker's White Plains office. He concentrates on medical malpractice and health care matters. His clients include doctors, nurses and other health care providers.

~ END ~

Ransomware and the Continuing Cyber Threats Facing the Healthcare Industry

By Betsy D. Baydala, Esq.

Nearly 80 million individuals' personal information was compromised when hackers breached one of the nation's largest insurers, Anthem, Inc. in 2015.[1] Later that year, 4.5 million individuals were also affected when hackers gained access to part of UCLA Health System's computer network where unencrypted patient information was stored.[2] To date, these are the largest breaches on a health insurer and healthcare provider, respectively.

According to NetDiligence's study of cyber claims submitted between 2013 and 2015, the healthcare industry was the most frequently breached sector, with the average payout totaling $726,000.[3] Hackers were the most frequent cause of loss (23%), followed by malware/virus (21%), staff mistakes (9%) and rogue employees (7%). Over 113 million records were affected due to breaches in the healthcare industry in 2015.[4] The message from criminals is clear: personal healthcare data is uniquely lucrative and, unfortunately, easily accessible with some technical prowess.

Over the past year, a new form of cyber-attack called ransomware has emerged and put the healthcare industry on the defensive. The FBI defines ransomware as "a type of malicious software cyber actors use to deny access to systems or data. The malicious cyber actor holds systems or data hostage until the ransom is paid. After the initial infection, the ransomware attempts to spread to shared storage drives and other accessible systems. If the demands are not met, the system or encrypted data remains unavailable, or data may be deleted."[5]

There has been an alarming increase in the number of ransomware attacks.



According to a U.S. government interagency report, since early 2016 there has been an average of 4,000 ransomware attacks a day.[1] This is a 300% increase since 2015 and represents the fastest growing malware threat.

Ransomware in the healthcare setting garnered national attention in February 2016, when hackers used malware to infect Hollywood Presbyterian Medical Center and seize control of its computers.[7] The hackers demanded 40 bitcoin (an anonymously traded digital currency valued at approximately $17,000) in exchange for a decryption key to regain access to the computer systems. Although the FBI does not encourage paying a ransom, the hospital determined that in the best interest of restoring normal operations, it paid the ransom to bring its system back online. The hospital alerted authorities and was able to regain control of its computer systems with the assistance of technology experts. Since the Hollywood Presbyterian incident, numerous other hospitals have been hit with ransomware attacks.[8]

Since the consequences of not having access to patient data during treatment can be dire, the healthcare industry must be prepared not *if* a ransomware attack happens, but *when* it happens.

Guidance from the U.S. Department of Health and Human Services' Office of Civil Right (OCR)

In order to help healthcare entities better understand and respond to the threat of ransomware, in July 2016, OCR released new HIPAA guidance on ransomware.[9] The guidance describes the role HIPAA has in assisting covered entities and business associates from preventing and recovering from ransomware attacks; how HIPAA breach notification processes should be managed in response to a ransomware attack; and how a ransomware attack can be detected.

I. Compliance with the HIPAA Security Rule can help prevent infections of malware, including ransomware

OCR highlighted the following required measures under the HIPAA Security Rule as some of the ways to help prevent the introduction of malware, including ransomware:

- Implementing a security management process, which includes conducting a risk analysis to identify threats and vulnerabilities to electronic personal health information (ePHI) and implementing security measures to mitigate or remediate those identified risks;
- Implementing procedures to guard against and detect malicious software;
- Training users on malicious software protection so they can assist in detecting malicious software and know how to report such detections; and
- Implementing access controls to limit access to ePHI to only those persons or software programs requiring access.

II. Compliance with the HIPAA Security Rule can help recover from infections of malware, including ransomware

In order to effectively recover from infections of malware, the HIPAA Security Rule requires covered entities and business associates to implement a data backup plan as part of maintaining an overall contingency plan.[10] Maintaining frequent backups and ensuring the ability to recover data from backups is crucial to recovering from a ransomware attack that denies access to data. Test restorations should be periodically conducted to verify the integrity of backed up data and provide confidence in restoration capabilities.

The HIPAA Security Rule also requires security incident procedures, including procedures for responding to and reporting ransomware attacks. Robust security incident procedures should include processes to:

- Detect and conduct an initial analysis of the ransomware;
- Contain the impact and propagation of the ransomware;
- Eradicate the instances of ransomware and mitigate or remediate vulnerabilities that permitted the ransomware attack;
- Recover from the ransomware attack by restoring data lost during the attack and returning to business as usual operations; and
- Conduct post-incident activities, which could include a deeper analysis of the evidence to determine if the entity has any regulatory, contractual or other obligations as a result of the incident, and incorporating any lessons learned into the overall security management process of the entity to improve incident response effectiveness for future security incidents.

III. Detecting a ransomware attack

Typically an entity is alerted to the presence of ransomware only after the ransomware has encrypted the user's data and alerted the user to its presence and demands payment. In some cases, however, an entity may notice early indications of a ransomware attack, such as:

- A user's realization that a link that was clicked on, a file attachment opened, or a website visited may have been malicious in nature;
- An increase in activity in the central processing unit of a computer and disk activity for no apparent reason;
- An inability to access certain files as the ransomware encrypts, deletes and re-names and/or relocates data; or
- Detection of suspicious network communications between the ransomware and the attackers' command and control server(s).

HIPAA's requirement that an entity's workforce receive appropriate security training can assist entities in preparing their staff to detect and respond to ransomware. If the entity believes a ransomware attack is underway, the entity should immediately activate its security incident response plan and contact its local FBI or U.S. Secret Service field office.

The presence of ransomware on a covered entity or business associate's computer systems is a security incident under the HIPAA Security Rule.[11] Once the ransomware is detected, security incident, and response and reporting procedures must be initiated.[12] A covered entity or business associate must also make a fact-specific determination whether the presence of ransomware was "a breach" under the HIPAA Rules.[13]

Key Mitigation Measures

The consensus among IT security experts is that a ransomware attack is more likely to happen on a healthcare entity than not. The best course of action for healthcare entities is to start guarding against and planning for a ransomware attack before it happens. Based on the guidance provided by the OCR and past ransomware incidents, at a minimum, the following steps should be taken to help mitigate the risks associated with ransomware attacks:

1. *Perform a risk assessment to identify threats and vulnerabilities.*
2. *Implement security measures to mitigate or remediate those identified risks.*

Security measures should be routinely updated and include continuous monitoring of the IT network as many malware infections go unnoticed. A simple and effective security measure is to require all system and network passwords be changed at regular intervals.

3. *Implement a data backup plan, which includes frequent backups and tests to ensure confidence in the ability to restore data.*
4. *Train and educate employees how to detect possible malicious activity and how to report same.*

Phishing scams, such as an email that looks like a routine business request but contains a malware threat – is the number one vehicle for ransomware, which means that negligent and uninformed employees put companies at risk. Employees need to be educated on the ransomware threat and how they can protect data. Risky employee behavior that should be stopped includes clicking on a website or advertisement for personal reasons, clicking on a website while knowing the link may not be secure, using business computers to access personal accounts, falling prey to a phishing scam, and using third-party applications (e.g., Dropbox, Spotify) on business computers.

5. *Have in place robust procedures to respond to and report a ransomware attack.*

Those most prepared to respond to a ransomware incident swiftly and intelligently are in the best position to have a favorable outcome.

Conclusion

The threat of ransomware and other cyber-attacks on the healthcare industry are real and not going away. These attacks have proven to be lucrative and anonymously executed. It is imperative that all health care providers – large and small – perform ongoing risk assessments to identify potential vulnerabilities to prepare for and defend against threats, and continually educate and train employees and staff on proper cyber hygiene.

REFERENCES ON PAGE 22

ABOUT THE AUTHOR



Betsy is an attorney practicing in the fields of cyber liability, medical malpractice, and healthcare law.

Betsy is a Certified Information Privacy Professional/United Stated (CIPP/US) and handles healthcare related cyber liability matters. Betsy has counseled healthcare clients on cyber issues, including HIPAA/ HITECH and regulatory compliance, pre-breach risk assessments and best practices. She is also well versed in breach response measures and regulatory investigations at the federal and state levels.

Betsy has experience representing major metropolitan area medical centers, podiatrists, psychologists, chiropractors, dentists, nurses, home health care attendants and various other health care professionals. Betsy handles all aspects of litigation and has tried cases to verdict.

Nondiscrimination Towards Transgender Patients

By Bryan Dildy, MPA, CPPS

Over the past decade there has been increasing awareness in equality and nondiscriminatory practices towards the LGBT community. This increase in awareness reached a monumental pinnacle in the 2015 *Obergefell v. Hodges* case, in which the United States Supreme Court legalized same sex marriages throughout the U.S. and its territories. The *Obergefell v. Hodges* case is just one recent example of securing equality for the LGBT community.

The expansion in equality efforts toward the LGBT community has unequivocally spilled over into the healthcare environment through various legislation and policies. For example, Section 1557 of the Affordable Care Act (ACA), which applies to healthcare entities, prohibits discrimination in health coverage and care towards protected classes including sex, age, and disability. Although Section 1557 prohibits discrimination, many healthcare facilities have failed to establish sound policies and procedures that address the evaluation and treatment of transgender individuals. This shortcoming can potentially lead to complaints against healthcare facilities which can subsequently lead to sanctions from the Office for Civil Rights (OCR).

There is also a risk that a Section 1557 complaint can lead to civil action litigation. A recent example of this can be seen in the 2015 *Rumble v. Fairview Health Services* case. In this case, Rumble, a biologically born female who identifies as male, alleged that a Fairview Emergency Room provider failed to provide adequate care. More specifically, Rumble alleges that because of his gender identity, the care he received was suboptimal and he was ignored by staff members. These allegations are a potential Section 1557 violation since gender identity is covered under the protected class definition of sex; therefore, supporting the merit of this case. There is the potential that this case of first impression will have a significant impact on case law and has led to a significant number of amici curiae from various advocacy and professional organizations. However, it must be noted that on December 31, 2016, the United States District Court of the Northern District of Texas issued a nationwide preliminary injunction that impacts the enforcement of Section 1557 claims (*Franciscan Alliance, Inc,m v. Burwell, et al,* 2016*).* As such, the *Rumble* case is currently postponed following the federal court injunction. The postponing of the *Rumble* case reveals that judicial clarity of Section 1557 is still needed.

The *Rumble* case is a strong indication that Section 1557 claims of discrimination towards the transgender community has the potential to cause civil action lawsuits. For this reason, it is important that healthcare organizations are compliant with Section 1557 regulations. Healthcare organizations must ensure that there are policies and procedures in place that address the management of individuals who present with a gender identity that differs from their biological identity. The Transgender Health Initiative of New York (THINY) has provided some recommendations that can assist hospitals and other health care providers in appropriately and respectfully treating individuals of the transgender community. Some of THINY recommendations include the following:

- Adopting and implementing a transgender non-discrimination policy that requires appropriate, respectable care to all patients regardless of gender identity
- Conducting hospital wide sensitivity training as it relates to the transgender community
- Creating admission and other medical paper work that allows a transgender patient to indicate their preferred name and sex
- Allowing transgender patients access to the bathroom that coincides with their gender identity

Healthcare entities can reduce exposure to malpractice and OCR complaints by considering THINY recommendations and by ensuring that they are abiding by state and federal nondiscriminatory regulations. Any questions or concerns as it pertains to your specific healthcare facility should be discussed with your hospital administration and general counsel.

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ABOUT THE AUTHOR



Bryan Dildy, MPA, CPPS, is currently a Risk Manager at White Plains hospital in Westchester, NY. He studied Criminal Justice and Forensic Psychology at St. John's University, before pursing his Master of Public Administration at Pennsylvania State University. He has earned his certification as a Certified Professional in Patient Safety. Previously, Bryan worked as a New York City Police Cadet and as a Civilian Complaint Review Board investigator. He has a strong passion for improving patient safety and quality improvement initiatives. He can be reached at bdildy@wphospital.org or 914-681-1044.



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CELEBRATING 25 YEARS

By Jonathan D. Rubin, Partner
Kaufman Borgeest & Ryan, LLP

In honor of Kisha Wright, we dedicated part of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) June 2017 annual conference in recognition of her 25 years of exceptional dedication to AHRMNY. Truly, there are no words to capture the essence of this extraordinary woman. I know I speak on behalf of our Board, Officers and Members, both past and present, when I state that AHRMNY is indeed synonymous with Kisha and there are so many reasons for that.

Over these many years of her close association with AHRMNY, Kisha has tirelessly worked with our board members and officers and with many members of various committees. She has contributed in so many ways with so much that makes our New York American Society for Healthcare Risk Management (ASHRM) Chapter special.

We are one of the largest and oldest national chapters in ASHRM and we have grown to over 275 members. We produce an esteemed and well known Risk Management Quarterly (RMQ) which I believe is one of the best risk management publications out there today and has been for many years. Every year we organize and present conferences, seminars and webinars on various timely topics of interest to our members in different venues across the metropolitan area. For all of this, Kisha has been the unifying thread. She is integral to these events as well as the publication of the RMQ. She is there at each planning step for RMQ and our events and offers guidance and advice on matters small and large. She is always available – 24/7 and is the most responsive person I have ever been associated with. Kisha knows so much about what makes AHRMNY successful and what works and does not with planning and organizing events. She is honest and candid when we need to hear that something will not work and she is encouraging and always positive when she thinks something that is planned or being done is worthwhile. Kisha is always upbeat and supportive of all the members and officers and has had to work closely with many different and sometimes difficult personalities over the years. With that she gets along with everyone and that is a truly special quality.





We have had events at a vast variety of venues over these many years – hospitals, hotels, private clubs etc. and Kisha has always been instrumental in maneuvering and providing support with the logistics and planning in all these places and locations. In recent years we have been doing more technological related programs such as webinars and Kisha is a pro of course with that as well and has made sure that our webinars run smoothly and effectively to relay timely information to our members and listeners.

AHRMNY has grown and accomplished much in the past 25 years and Kisha has been an essential part of our organization during that time. Kisha has been the one consistent person that has been there for AHRMNY and as the heart and soul of the organization it is vitally important that she be honored and recognized for her amazing service and be broadly and enthusiastically thanked. We truly and without reservation could not do what we do without her and we hope and pray 🙂 that we will have the privilege to have Kisha continue to work with all of us connected to AHRMNY and do all that she does now and well into the future.



The Increased Threat of Hospital Liability After Munsey v. Delia

By Eric Broutman, Esq. and Carolyn Wolf, Esq.

In 1975 the Supreme Court of United States ruled in O'Connor v. Donaldson[1] that a hospital may not involuntarily confine a psychiatrically ill patient if that patient could live safely in the community. It followed from that ruling that a psychiatric patient may be involuntarily hospitalized only where that patient presents a danger to self or others due to mental illness. In order to meet this constitutional standard, New York State allows for numerous court hearings, at statutorily required times, where a Court must determine if the dangerousness standard is met. It is the hospital's, not the patient's, obligation to request the court hearing within the statutorily defined time limits. See generally, New York Mental Hygiene Law Article 9.

This naturally begs the question: What happens if the hospital fails to request a court hearing when statutorily required to do so? Prior to 2015, a series of Appellate Courts ruled, fairly unanimously, that the appropriate remedy was an immediate hearing to determine if the patient was mentally ill and dangerous. In essence, the hospital suffered no penalty or increased potential for liability by continuing to retain a patient past a statutory deadline.

In 2015, the Court of Appeals (the highest court in the State of New York) decided the case of Munsey v. Delia[2], which reversed course and ruled that the appropriate remedy is the patient's immediate discharge, and not an immediate hearing. The facts of Munsey are very instructive.

In the case, the hospital failed, for six weeks, to apply to court to seek the continued retention of a patient. The particular patient in question was quite dangerous, having struck his treating psychiatrist and other staff members on numerous occasions. The Court of Appeals concluded that the prior remedy, an immediate hearing, was not sufficient to protect the constitutional due process rights of patients, but rather the appropriate remedy is the patient's immediate discharge, regardless of the patient's clinical condition. Indeed, the discharge should occur right away, without any presentation from the psychiatrist regarding the condition of the patient, the feasibility, or safety, of immediate discharge. Plainly put, where the hospital does not timely file for a court hearing the patient will be allowed to leave the hospital, without further inquiry.

This reversal in Court remedies, going from a hearing to an immediate discharge, significantly increases the potential for liability for both psychiatrists and hospitals if the patient becomes self-injurious or injures another after a court ordered release. In the Pre-Munsey world, where the hospital was allowed to conduct a hearing on the merits, the hospital and psychiatrist were absolutely insulated from future liability if the Court deemed that the patient should not be involuntarily committed, despite the evidence presented by the psychiatrist; the reason being that the Court decided to release the patient against the advice of the psychiatrist and hospital. Under present circumstances, where the patient is immediately discharged because of a simple administrative error, liability is a real possibility.

This article will discuss the increased potential for liability on the part of hospitals and psychiatrists after the Munsey decision and how to protect against making an error that will likely require the discharge of a patient who otherwise would not be discharged.

Involuntary Hospitalization and Time Deadlines

Inpatients in a psychiatric hospital largely fall into two categories, voluntary and involuntary. Voluntary patients may theoretically remain in a hospital indefinitely without court approval, but if that patient requests release from the hospital, and the hospital wants to retain the patient, the hospital must submit an application for a court hearing within 3 days.[3]

Involuntary patients may remain in a hospital without court approval for up to 60 days, whereupon the hospital must seek court approval for continued hospitalization.[4] Moreover, during this time the patient may make numerous requests for a court hearing to challenge the validity of the hospitalization.[5] If such a request is made, the hospital must submit the request to court immediately.

The Law Prior to Munsey

Prior to Munsey when a hospital made an error and failed to apply for a required hearing the law called for an immediate hearing to determine if the patient met the criteria for involuntary hospitalization. Specifically, the Court would hear evidence as to whether the patient was mentally ill and dangerous. The reasoning behind Courts' decisions prior to Munsey was that the public had such a significant interest in safety from potentially dangerous patients that it overrode the individual's interest in a timely hearing.

Considering the number of involuntary patients treated every year, hospitals are largely successful in ensuring that all required court hearings are indeed requested.

Nonetheless, errors do occur. Prior to Munsey, so long as these mistakes remained infrequent it did not present a significant issue. The Court was still required to conduct a hearing on the merits, and if the Court concluded that the patient was dangerous as a result of mental illness the Court would authorize a continued retention. On the other hand, if the Court concluded that the patient did not meet these criteria and discharged the patient, the psychiatrist and hospital was absolved of any potential liability because it was the Court that ordered the discharge. In the event a hospital continually flouted statuary deadlines that hospital could potentially lose their operating license from the Office of Mental Health, or suffer other administrative penalties.

The Law After Munsey

After Munsey, Courts now, in most circumstances, will require the immediate release of a patient if the hospital fails to adhere to the time demands of the Mental Hygiene Law even without the Court having an opportunity to address the question of the patient's mental illness and dangerousness. In other words, it does not matter if the patient is mentally ill or dangerous. The only question is whether or not the statutory deadlines were complied with.

The Court of Appeals in Munsey held that even under the circumstanced present, where the patient was flagrantly dangerous in the hospital, the appropriate remedy should have been the patient's immediate release due to the hospital's error.

While the ruling seems harsh, the Munsey Court does soften its stance somewhat by stating that there are other avenues a hospital may pursue to retain a dangerous patient where it has failed to timely apply for a court hearing. Moreover, the Court in Munsey stated that not every violation of the Mental Hygiene Law shall result in the immediate release of a patient. However, the parameters of this limiting language have not yet been defined. For instance, what violations do result in the immediate release of a patient and what violations do not? Does missing a deadline by a single day, as opposed to six weeks as was the case in Munsey, result in release? These questions remain unanswered and will require further litigation and Court rulings to fully flesh out their boundaries.

Potential Hospital Liability

A fictitious case example can be instructive in demonstrating the potential issues that may arise since Munsey was decided. Patient, Henderson Richard, was admitted to the hospital on June 27, 2016, pursuant to Mental Hygiene Law §9.27 ("Two Physician Certificate" status). The hospital could legally retain the patient for 60 days, until August 26, 2016, without additional court approval. During his hospitalization Mr. Richard required numerous administrations of emergency medication for agitated and threatening behavior, including threatening his treating psychiatrist with murder. Mr. Richard suffered from paranoid delusions believing that others are out to hurt him and therefore he often lashed out in perceived self-defense, hence the numerous violent episodes in the hospital. At the 60-day mark Mr. Richard's symptoms had not yet resolved, including his violent outbursts. It was the hospital's intention to continue his retention and transfer him to a long-term facility. Unfortunately though, due to an administrative error, the hospital failed to apply for Mr. Henderson's continued retention in the time required. As a result, his Mental Hygiene Legal Service attorney filed a writ of habeas corpus, a legal motion seeking his immediate release pursuant to the Court's decision in Munsey. Despite Mr. Richard's clear psychotic and violent behavior the Court ruled in Mr. Richard's favor and ordered that he be released immediately from the hospital due to the hospital's failure to apply for further retention within a certain time frame.

It is precisely this scenario that poses significant liability issues for a hospital. One could also replace the fictional Mr. Richard's violent behavior with suicidal behavior. We must then ask the question, what liability may the hospital suffer if a patient like the fictional Mr. Richard is released from the hospital due to hospital's administrative error and then harms someone in the community, or himself? The answer is potentially significant monetary damages.

It is generally understood that medical doctors owe a duty of care to their patients. However, physicians are not held liable for mistakes when the treatment offered has a proper medical foundation. A physician's duty "is to provide the level of care acceptable in the professional community in which he practices. He is not required to achieve success in every case and cannot be held liable for mere errors of professional judgment."[6]

Hence, while hospitals and psychiatrists will not be liable for errors made in good faith within the realm of professional judgment, it is hard to see how failing to timely apply for a court hearing and thus the court mandated release of a patient meets "the level of care acceptable in the community." It is likely that a patient released under this scenario, who then engages in self-injurious behavior or harms himself through neglect because of an inability to care for self may have a valid cause of action against the treating psychiatrist and hospital for malpractice.

As for patients who are released and then go on to harm others, the analysis is similar because the duty owed to third parties by a psychiatrist or mental health practitioner is somewhat different than that owed by a non-psychiatrist physician. For psychiatrists, the duty

owed is not only to patients but to the outside public as well where the patient is involuntarily confined.[7] This duty was made clear in the famous case of Tarasoff *v. Regents of University of California*[8] where a therapist was held liable for a patient's actions. The patient has been threatening to kill a college student during a therapy session and then went on to kill that very student. The Tarasoff Court concluded that the therapist had a duty to warn the student that was threatened and ultimately killed. Indeed, New York implicitly recognized the potential for liability when it amended the Mental Hygiene Law in 1984 to authorize mental health providers to warn individuals that may be in danger without violating confidentiality.[9]

Providing a Tarasoff type warning in a Munsey created dilemma may only be possible in limited situations, however. Only if the patient in question is fixated on a particular individual will there be someone to warn. In the more likely scenario the patient is dangerous to the public at large and not a specific individual person.

A review of verdicts and settlements in cases where hospitals and psychiatrists have been found liable for prematurely releasing a patient is instructive. In 2009, an Arizona jury awarded $1,500,000 against a psychiatrist and hospital where they discharged who then went on to murder his grandparents. The patient was medication noncompliant and expressed a multitude of violent fantasies.

In 1994, a Missouri jury awarded the plaintiffs, the husband and children of the decedent patient, $705,000 where the hospital discharged the patient after she was depressed and expressed suicidal statements. The patient killed herself four days after discharge.

In 1992, a North Carolina Jury awarded the plaintiffs, the decedent's parents, $3,000,000 where the hospital discharged the patient after his insurance ran out despite the fact that the patient was still expressing suicidal statements. The patient shot himself just hours after his discharge.

To avoid liability, and to continue to treat patients that need treatment, hospitals must enhance their efforts to track the legal status of patients. The hospital must ensure that it applies for every statutory or court mandated hearing. There are law firms and outside organizations that have developed tracking and notification software to assist in these efforts and it is recommended that hospitals investigate their usefulness and viability in their own situations. Moreover, hospitals must ensure that they properly train their staff on the various time requirements in the Mental Hygiene Law, the consequences of missing those time deadlines, and how to properly apply to court for the required hearings.

But, even with more vigilant tracking software and the training of staff, mistakes will occur. Human beings simply are not perfect, no matter how hard we try. If a hospital finds itself in a Munsey type situation, where a deadline was missed and it appears likely that a dangerous patient will be released; good practice dictates seeking counsel from experienced mental health attorneys to craft a plan that comports with Munsey to either thwart the release of the patient, or to seek the immediate readmission of the patient. This will not only avoid liability on the part of the hospital, but will also further the primary goal of the hospital, to treat the mentally ill. Recall that the Court of Appeals in Munsey stated that there are other avenues a hospital may pursue to retain a dangerous patient where it has failed to timely apply for a court hearing. Munsey stated, "it is incumbent upon the facility to commence a new article 9 proceeding in compliance with the strictures of the Mental Hygiene Law."[10] The key is determining what Article 9 proceedings the Court was referring to and how exactly to initiate such a proceeding.

Experienced mental health legal counsel can assist New York hospitals to retain dangerous mentally ill patients as well as provide legal counsel to avoid potentially costly liability and negative press in the event of an adverse outcome after a patient is released under these circumstances.

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ABOUT THE AUTHORS



Eric Broutman is a Partner at Abrams, Fensterman, Fensterman, Eisman, Formato, Ferrara, Wolf & Carone, LLP. His practice focuses on the areas of mental health and employment law. Mr. Broutman has been practicing in the field of Mental Health Law for over a decade, representing patient and hospital clients. Notably, Mr. Broutman has been involved in shaping the parameters of the Mental Hygiene Law in numerous Appellate and Court of Appeals matters. He is a member of the New York State Bar and is admitted to practice in the United States District Courts for the Southern and Eastern Districts of New York.



Carolyn Wolf, Esq., is an Executive Partner at Abrams, Fensterman, Fensterman, Eisman, Formato, Ferrara & Wolf, LLP and Director of the Firm's unique Mental Health Law Practice. Ms. Wolf represents mental health and health care professionals and institutions on all issues related to mental health, substance abuse and capacity. Her main focus is working with individuals and families to help them navigate through the mental health, health care, and criminal law systems in order to formulate a working plan of action using her mental health tool kit to obtain referrals, services and support, as well as using her background and contacts as a former hospital administrator.

Concurrent and Overlapping Surgery: Addressing the Risks

By Kathleen Shostek, RN, ARM, FASHRM, CPHRM, CPPS

Concurrent and overlapping surgery has been described as when a surgeon begins a second operation, leaving the rest of the first procedure to another surgeon or practitioner to complete.[1] Long a common practice in teaching hospitals, concurrent and overlapping surgery has been thought of as an acceptable way to optimize surgeons' skills, reduce delays, and allow surgeons in training or assistants to complete routine procedures. However, the practice came under scrutiny when Boston Globe reporters published an investigative report on the topic, spurring state and federal investigations. The report detailed patient-related events and subsequent complaints and lawsuits, and described concerns that had been raised by surgeons to hospital administration about the practice.[2] Professional and public outcries prompted the American College of Surgeons (ACS) to address concurrent and overlapping surgery by revising its Statements on Principles to address the practice.[3] With patient safety as a primary consideration, and the desire to avoid claims and lawsuits, hospitals where concurrent or overlapping surgery is performed are reexamining their surgical policies and practices.

Definitions: What's the difference?

In its Statements on Principles, ACS makes an important distinction between **concurrent** surgery and **overlapping** surgery by ascribing the term "simultaneous" to concurrent surgery. The ACS statement notes that when the critical or key components of the procedures for which the primary attending surgeon is responsible are occurring all or in part at the same time, it is considered simultaneous. ACS goes on to state that the primary attending surgeon's involvement in concurrent or simultaneous surgeries on two different patients in two different rooms is inappropriate.

The term overlapping surgery is used by ACS to describe surgeries performed by the primary attending surgeon in two situations. One situation is when the critical elements of the first operation have been completed by the primary attending surgeon, who then starts a second operation in another operating room. In this circumstance, a qualified practitioner completes the noncritical components of the first operation, such as wound closure. The second situation is when the key or critical elements of the first operation have been completed and the primary attending surgeon is performing key or critical portions of a second operation in another room. ACS notes that, when this occurs, the primary attending surgeon must also assign immediate availability in the first operating room (OR) to another attending surgeon.

In both situations, the critical or key components of an operation are to be determined by the primary attending surgeon. An approach by one hospital to define critical components, described in the Senate Finance Committee White Paper, *Concurrent and Overlapping Surgery*,[4] uses Current Procedural Terminology (CPT®) codes for hip procedures; the critical portions identified include finalizing bone cuts or bone preparation, implant trialing, and final placement of implants.

Considerations for Risk Management

There are a number of ethical, risk management and patient safety issues surrounding concurrent and overlapping surgery. Sedgwick healthcare risk management consultants have encountered several of these issues and concerns while performing surgical risk assessments and making observations in the OR. We have also received calls from our clients asking for information, resources and advice on the topic. Some of these issues and concerns have included the following:

- Longer anesthesia time for patients waiting for the attending surgeon, when delayed in the first procedure
- Lack of patient awareness (consent) regarding what portions of the surgery are being performed by which surgeons or practitioners involved in the procedure
- Inadequate supervision of surgical residents and surgical assistants, and scope of practice creep when the primary surgeon leaves the OR for a second procedure
- OR nurses reporting fears of "patient abandonment"
- Inadequate pre-procedure briefings and the absence of surgical debriefs

In general, ethics and informed consent, regulatory compliance, professional practice guidance, and surgical department policies are all areas that deserve special risk management attention when considering your own organization's concurrent and overlapping surgeries.

Informed Consent Requirements and Compliance

It is common in academic and teaching facilities for patients to give general consent during their admission to have students and residents participate in their care.

More specific consent forms, obtained later, often contain language permitting the attending surgeon and his or her assistants or delegates to carry out procedures related to the planned surgery. However, there is often inconsistency regarding the amount and type of information provided to patients regarding the involvement of those other than the attending surgeon. One study reported that, while patients preferred having detailed information about resident participation in their procedures, consent rates declined significantly when such information was provided.[5]

When addressing informed consent, the ACS Statements on Principles guide the surgeon to include, "a discussion of the different types of qualified medical providers who will participate in their operation and their respective roles." The Centers for Medicare & Medicaid Services (CMS) does not specifically address informed consent for concurrent or overlapping surgery. However, CMS' interpretive guidelines include a statement about the elements of a well-designed informed consent process that includes, "whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery,...and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner." CMS also includes recommended patient discussion items for surgeries in which residents will perform important parts of the surgery.[6] In addition, various statutory requirements for informed consent apply.

Examples of statements in surgical policies that address disclosure include:

- **"If the surgeon will not be present for any portion of the surgical procedure, the patient must be informed"**
- **"Overlapping surgery should be disclosed to the patient during the informed consent process"**

In December 2016, a U.S. Senate Finance Committee published its report on concurrent and overlapping surgeries, calling for additional measures and oversight of the practice.[4] The report noted that just half of the hospital policies reviewed by the committee included a requirement to inform patients that their procedure would be scheduled as an overlapping one. Also, experience with medical malpractice claims shows that, in cases involving residents or surgical assistants, the plaintiffs have often claimed they were unaware of the roles and responsibilities of providers involved in their procedures. It was only during discovery and record review that they became aware of who performed what part of the surgery.

More on Regulations and Compliance

CMS permits providers to bill the Medicare program for up to two simultaneous or overlapping surgeries, but the regulations note that the surgeon must be available for "critical" portions of both operations. CMS does not define what is meant by critical.[7] The Medicare rules include requirements for another surgeon to be immediately available when the attending surgeon leaves to begin a second procedure and note that the attending surgeon must document his or her presence for the surgery.

At the state level, the Massachusetts Board of Registration in Medicine recently approved a rule to regulate the practice of concurrent surgery that mirrors CMS' rules.

According to a 2015 Boston Globe report, a Wisconsin medical school paid $840,000 to settle a lawsuit alleging that neurosurgeons illegally billed Medicare for simultaneous spine surgeries largely done by unsupervised medical residents. Similar settlements have been made by other facilities and providers.[8]

ACS Guidelines

The ACS principles note that when the primary attending surgeon is not present, nor immediately available, another attending surgeon should be assigned as being immediately available. This is in keeping with the Medicare requirements that the surgeon be available for critical portions of both operations, which cannot occur simultaneously.

In the case of operations where several surgical specialists are involved, each may only be present for the component of the operation for which he or she is responsible. The ACS principles state that, in these operations, an attending surgeon must still be immediately available for the entire operation.

Within the ACS principles, "critical or key" portions of an operation are defined as "segments when essential technical expertise and surgical judgment are required, as determined by the attending surgeon"; "physically present" means that the attending must be in the same room as the patient; and "immediately available" means he/she must be reachable and able to return to the OR immediately.

The U.S. Senate Finance Committee report on concurrent and overlapping surgeries noted above provides a comparison of CMS and ACS guidance and can be found here: http://www.finance.senate.gov/imo/media/doc/Concurrent%20Surgeries%20Report%20Final.pdf.

Surgical Department Policy Considerations

It is important to consider a number of things when developing policies or reviewing existing policies on concurrent or overlapping surgery, including the applicable regulations and professional practice guidelines discussed above. Also, it is key to review available studies on the safety and efficacy of the practice as support for your own decisions. For example, a recent study published by the Mayo Clinic on over 10,000 overlapping surgeries revealed no difference in the rates of postoperative complications or deaths within a month after surgery.[9] One earlier study involving 3,000 simultaneous cardiothoracic surgeries at the University of Virginia found no negative impact on surgical complications, length of hospital stay, or operative mortality.[10]

As there has been a general dearth of information in the literature on concurrent surgery and its effect on patients and outcomes, surgical departments must define practices and policies with patient care and safety at the forefront.

Once developed, it is essential to communicate policies to the surgical, teaching, scheduling and nursing staff. Implement a process to review surgeon compliance and provide feedback to physicians and department chairpersons. Establish a clear means of communication and chain of command for OR nurses and surgical support staff to ask questions and voice concerns.

Recommendations for addressing concurrent surgery risks include:

- Have the surgical executive committee define concurrent or overlapping surgery, identify what surgeries are acceptable for concurrent or overlapping performance, and specify the "critical parts" of the operation.
- Implement a comprehensive informed consent process – the process should include a discussion about which surgeons and other surgical practitioners will perform what parts of the operation; consent practices and forms should be reviewed with medical staff and legal counsel.
- Establish a process to ensure that a surgeon is immediately available to return to the OR as necessary.
- Ensure all surgeons' entry and exit times from the OR are documented, noting the portions of the procedure when the surgeon was present and the extent of their involvement.
- Address application of standard safety procedures such as the universal protocol for prevention of wrong patient, procedure or site surgeries, and responsibility for conducting pre-procedure briefs and post-procedure debriefs.
- Review any unexpected outcomes in cases involving concurrent performance or overlaps, as well as any extended anesthesia times while awaiting a surgeon's arrival.

Healthcare risk managers can work with surgeons and clinical staff, legal counsel and administrators to proactively address the patient safety, clinical and regulatory issues that currently surround the practice of concurrent or overlapping surgery. Bringing the topic to an appropriate decision-making body or committee, with related guidelines and regulations for review and recommendations for action, can foster the development of policies that aim to protect patient safety, set guidance for providers, and mitigate risks for the organization.

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ABOUT THE AUTHOR



Kathleen Shostek is Vice President Healthcare Risk Management at Sedgwick. She is an industry recognized patient safety and risk management professional with over 25 years of experience. She provides consultative services to improve and enhance risk management and patient safety programs. An emphasis is placed on risk reduction techniques and innovative approaches to improve patient safety and reduce preventable harm. Ms. Shostek is also an ASHRM faculty member for the society's patient safety certificate course and is a national speaker on topics related to patient safety and risk management.

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MEMBER SPOTLIGHT

Soroya Pognon, MSW MHA CPHRM - Hospitals Insurance Company



Soroya Pognon has an extensive background in social work having worked in behavioral health for ten years as a clinician and Director of Risk Management and Quality. She joined Hospitals Insurance Company (HIC) in 2014 as a Clinical Patient Safety Analyst working to ensure obstetric provider compliance with professional and hospital best practice standards. Soroya obtained CPHRM designation February 2017. She is a current member of AHRMNY and ASHRM.

Carolyn Reinach Wolf, Esq. - Abrams Fensterman, et al



Executive Partner, Carolyn Reinach Wolf was honored as a Long Island Business and Professional Leader by UJA – Federation of New York. The award was presented by Associate, Jamie Rosen at the Long Island Business and Professional Leaders "Connect and Celebrate" Dinner at the Old Westbury Hebrew Congregation on May 10th. Carolyn was recognized for the development of one of the only mental health law practices in the country as well as her zealous advocacy for her clients.

Robin Maley, RN MPH MS CPHRM CPHQ - Sedgwick



Robin Maley has joined Sedgwick as Senior Vice President, Healthcare Risk Management and Patient Safety. In this role, she is responsible for overseeing and providing consultative services to improve healthcare risk management and patient safety programs at health care organizations and among health care providers. She is also a recent recipient of a Masters of Science degree from the Mount Sinai Icahn School of Medicine Health Care Delivery Leadership Program, designed to prepare students for the rapidly evolving changes within the current health care industry.

Denise Shope, RN MSHA ARM CPHRM FASHRM - RCM&D



Denise Shope will be speaking at the ASHRM Annual Conference in Seattle on October 16, 2017. Her topic is Enterprise Risk Management: Using benchmarking analytics to develop and implement your ERM Program—a case study. In addition Denise will be one of the ASHRM faculty for the ASHRM Enterprise Risk Management Certificate program presented at ASHRM's preconference. Denise is a risk management consultant at RCM&D.

Bonnita (Bonnie) Boone - Arthur J. Gallagher & Co.



Bonnie Boone was recently nominated and honored for her commitment to African American females in the commercial insurance industry by the Insurance Industry Charitable Foundation (IICF). IICF acknowledges women who are personally committed to women's advocacy and the advancement & mentoring of women. Bonnie was also named an Elite Women of Insurance 2017 by Insurance Business Magazine.

As Executive Vice President at Arthur J. Gallagher, Bonnie oversees Gallagher's healthcare practice in the New York and Chicago regions.

Jose L. Guzman, RN MS CPHRM DFASHRM - Hudson Insurance Group



Jose was an Assistant VP at Hudson Insurance Group and has been promoted to Vice President & Managing Director. Jose joined Hudson in 2015 and in his short tenure has been instrumental in developing a Healthcare Risk Management platform that includes monthly webinars and quarterly newsletters. Jose and his team have also designed and implemented a risk management software platform that provides online patient and workplace safety training to our Healthcare clients. In his new role, Jose will be responsible for expanding the healthcare risk management initiatives and he and his team will focus on further developing internal reference guides, site and patient assessment procedures as well as supporting our growing ancillary business.

MEMBER SPOTLIGHT

Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (from CMS.gov)

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Purpose

The final rule published 9/16/2016 by the Centers for Medicare & Medicaid Services establishes national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to plan adequately for both natural and man-made disasters and coordinate with federal, state, tribal, regional and local emergency preparedness systems.[1] It will also assist providers and suppliers to adequately prepare to meet the needs of patients, residents, clients and participants during disasters and emergency situations. The regulations are intended to provide consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare and Medicaid participating facilities, and establish a more coordinated and defined response to natural and man-made disasters. These requirements are part of the federal health and safety standards that long-term care facilities must meet in order to participate in the Medicare or Medicaid programs by the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS).

Dates

Effective date: These regulations are effective on November 15, 2016.

Implementation date: These regulations must be implemented by November 15, 2017.

Target audience: Health care organizations that are CMS providers and suppliers and other interested stakeholders. The following are the statutory and regulatory citations for the providers and suppliers for which CMS is issuing emergency preparedness regulations:

Religious nonmedical health care institutions (RNHCIs) — section 1821 of the Act and 42 CFR 403.700 through 403.756

Ambulatory surgical centers (ASCs) — section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.2 and 416.40 through 416.52

Hospices — section 1861(dd)(1) of the Act and 42 CFR 418.52 through 418.116

Inpatient psychiatric services for individuals under age 21 in psychiatric residential treatment facilities (PRTFs) — sections1905(a) and 1905(h) of the Act and 42 CFR 441.150 through 441.182 and 42 CFR 483.350 through 483.376

Programs of all-inclusive care for the elderly (PACE) — sections 1894, 1905(a), and 1934 of the Act and 42 CFR 460.2 through 460.210

Hospitals — section 1861(e)(9) of the Act and 42 CFR 482.1 through 482.66

Transplant centers — sections 1861(e)(9) and 1881(b)(1) of the Act and 42 CFR 482.68 through 482.104

Long-term care (LTC) facilities — skilled nursing facilities (SNFs) — under section 1819 of the Act, nursing facilities (NFs) — under section 1919 of the Act, and 42 CFR 483.1 through 483.180

Home health agencies (HHAs) — sections 1861(o), 1891 of the Act and 42 CFR 484.1 through 484.55

Comprehensive outpatient rehabilitation facilities (CORFs) — section 1861(cc)(2) of the Act and 42 CFR 485.50 through 485.74

Critical access hospitals (CAHs) — sections 1820 and 1861(mm) of the Act and 42 CFR 485.601 through 485.647

Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services — section 1861(p) of the Act and 42 CFR

Community mental health centers (CMHCs) — section 1861(ff)(3) (B)(i)(ii) of the Act, section 1913(c)(1) of the PHS Act, and 42 CFR 410.110

Organ procurement organizations (OPOs) — section 1138 of the Act and section 371 of the PHS Act and 42 CFR 486.301 through 486.348

Rural health clinics (RHCs) — section 1861(aa) of the Act and 42 CFR 491.1 through 491.11; Federally Qualified Health Centers (FQHCs)—section 1861(aa) of the Act and 42 CFR 491.1 through 491.11, except 491.3

End-stage renal disease (ESRD) facilities — sections 1881(b), 1881(c), 1881(f)(7) of the Act and 42 CFR 494.1 through 494.180

Background

Numerous natural and man-made disasters have challenged the U.S. over the past several years. Disasters can disrupt the environment of health care and change the demand for health care services; therefore, it is essential that health care facilities integrate emergency management into their daily functions and values.

Background

Previous events include the 2009 H1N1 influenza pandemic, the 2001 anthrax attacks, the tornados in 2011 and 2012, and Superstorm Sandy in 2012. In 2014, the U.S. faced a number of new and emerging diseases, such as MERS-CoV and Ebola, and a nationwide outbreak of Enterovirus D68. CMS believes that finalizing the emergency preparedness rule is an important part of improving the national response to infectious disease threats.

Health care providers have raised concerns about their safety when caring for patients with Ebola and other infectious diseases, citing the need for advanced preparation, effective policies and procedures, communication plans, and sufficient training and testing, particularly for personal protection equipment (PPE). The response highlighted the importance of establishing written procedures, protocols and policies ahead of an emergency event. With the finalization of the emergency preparedness rule, this type of planning will be mandated for Medicare and Medicaid participating hospitals and other providers and suppliers through the conditions of participation (CoPs) and conditions for coverage (CfCs) established by this rule.

Summary of the Major Provisions

The final rule addresses the three key essentials that CMS believes are necessary for maintaining access to health care services during emergencies:

1. Safeguarding human resources
2. Maintaining business continuity
3. Protecting physical resources

CMS believes that current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

Four core elements have been identified that CMS believes are central to an effective and comprehensive framework of emergency preparedness requirements for the various Medicare and Medicaid participating providers and suppliers. The four elements of the emergency preparedness program are:

1. **Risk assessment and emergency planning:** Facilities will be required to perform a risk assessment that uses an "all-hazards" approach prior to establishing an emergency plan. The all-hazards risk assessment will be used to identify the essential components to be integrated into the facility emergency plan based on vulnerabilities identified. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the provider or supplier and considers the particular types of hazards most likely to occur in their areas. These may include, but are not limited to, care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and interruptions in the normal supply of essentials, such as water and food.

2. **Policies and procedures:** Facilities will be required to develop and implement policies and procedures that support the successful execution of the emergency plan and risks identified during the risk assessment process.

3. **Communication plan:** Facilities will be required to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. Patient care must be well-coordinated within the facility, across health care providers, and with state and local public health departments and emergency management agencies and systems to protect patient health and safety in the event of a disaster. The use of an Incident Command System and backup means of communication in the event of power or connectivity loss should be considered in the plan.

4. **Training and testing:** Facilities will be required to develop and maintain an emergency preparedness training and testing program. A well-organized, effective training program must include initial training for new and existing staff in emergency preparedness policies and procedures as well as annual refresher trainings. The facility must offer annual emergency preparedness training so that staff can demonstrate knowledge of emergency procedures. The facility must also conduct drills and exercises, including at least one full community drill to test the emergency plan to identify gaps and areas for improvement. Maintaining documentation of these drills and employee training sessions is necessary to show evidence of employee and facility readiness. After-action report/improvement plan (AAR/IP) following the Homeland Security Exercise and Evaluation Program (HSEEP) formula are suggested methodologies.

What to do

Medicare and Medicaid participating providers and suppliers should take the following actions to prepare for compliance with this rule by the effective date (11/15/2017):

Read the new rule from CMS in the Federal Register https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html

Complete a gap assessment of current status to the requirements under the new rule to determine if any gap exists.

Create a plan to address gaps that may have been found in the assessment.

Monitor action plan to closure.

Willis Towers Watson is available to help support your efforts if you would like to discuss.

For additional information or assistance contact your Willis Towers Watson Client Relationship Manager or:

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ABOUT THE AUTHORS



Charles W. Brandt II, CPS CFPS CBCP CBCLA MS is Vice President, Senior Risk Control Consultsant at Willis Towers Watson. Charles's career spans over 28 years as a practicing professional within the Insurance Risk Management industry. He is a technical expert specializing in the development of multi-disciplined risk management solutions for complex risk exposures in the areas of occupational safety & health, enterprise risk management, emergency planning and security management. Charles is an active member of the American Society of Safety Engineers (ASSE), the Association of Contingency Planners (ACP) and a certified trainer of the ALICE "Active Shooter" program.



John Barghout is Senior Vice President and Atlantic Region Risk Control Director at Willis Towers Watson. John has 30 years of property risk control industry experience servicing clients based in North America. In addition to his risk control expertise, John has also developed peer review business continuity plans for global clients in healthcare, retail, real estate, aerospace higher education, and entertainment. John is a member of the National Fire Protection Association (NFPA) and past Director of the Connecticut Valley Chapter of the Society of Fire Protection Engineers (SFPE).



Brian Kincaid, CSP, MBA, CHSP is Senior Risk Control Consultant at Willis Towers Watson. Brian has extensive experience spanning more than 25 years in the areas of occupational safety and health, risk control, industrial hygiene, ergonomics, safety management, fleet safety and OSHA compliance. Brian is a professional member of the American Society of Safety Engineers (ASSE) and of the American Industrial Hygiene Association (AIHA). Brian is also past President of the Lower Delaware Valley Chapter ASSE.

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System VP, Risk Management, Patient Safety & Chief Privacy Officer
Catholic Health Services of Long Island
lesli.giglio@chsli.org

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Tiffany Wickes-DeMillio, RN MBA CPHRM LNC
Director, Risk Management/Regulatory Affairs, Patient Safety/Privacy Officer
tiffany.wickes-demillio@chsli.org

Past President
Mary Steffany, RN MA ARM CPHRM FASHRM
Senior Healthcare Risk Consultant
Zurich
mary.steffany@zurichna.com

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Lewis Johs Avallone Aviles, LLP
dcbraverman@lewisjohs.com

Secretary
CaraMia Hart, Esq.
Partner
Dopf, PC
caramiahart@icloud.com

DIRECTORS

Bonnie Boone
Executive VP, Midwest Region
Arthur J. Gallagher & Co.
bonnie_boone@ajg.com

Michael Brendel
Director, Professional Liability Claims
Sedgwick Claims Management Services, Inc.
michael.brendel@sedgwick.com

DIRECTORS (continued)

Linda Foy, CPHRM
AVP, Enterprise Risk Management
Catholic Health Services of Long Island
linda.foy@chsli.org

Victor Klein, MD MBA CPHRM FACOG FACMG FASHRM
System Director, Quality & Patient Safety/OB GYN
Northwell Health
hirisk3@aol.com

Diane Longo, ARM, LHRM, CPHRM
Director, Corporate Insurance/Non-Clinical Risk
NewYork-Presbyterian/Lawrence Hospital
dlongo@lawrencehealth.org

Robert Marshall, CPCU RPLU AIC
Client Advocate, Corporate Risk & Insurance Healthcare Practice
Willis Towers Watson
robert.marshall@willistowerswatson.com

Robert D. Martin, Esq.
Senior Litigation Attorney
Tromello McDonnell & Kehoe
robert.martin@cna.com

Pamela Monastero, MBA
Asst Director, Patient Safety/Risk Management
NYU Lutheran Medical Center
pamela.monastero@nyumc.org

Ruth A. Nayko, RN MBA CPHRM CPHQ CPPS
AVP, Healthcare Risk Management Group
AWAC Services Company
ruth.nayko@awacservices.com

Linda A. Rowett, RN BSN
Interim Director, Risk Management
Interfaith Medical Center
lrowett@msn.com

Gehan Soliman, CPHRM
Director, Risk Management
Robert Wood Johnson University Hospital
Gehan.Soliman@rwjbh.org

EMERITUS BOARD MEMBERS

Jose L. Guzman, Jr., RN MS CPHRM DFASHRM
VP and Managing Director, Risk Management
Hudson Insurance Group
jguzman@hudsoninsgroup.com

Grace Rose Langan, MSN RN
Senior Director, Regulatory Affairs
NYU Lutheran Medical Center
GraceRose.Langan@nyumc.com

Robin Maley, RN MPH CPHRM CPHQ
SVP, Risk Management & Patient Safety
Sedgwick Claims Management Services, Inc.
Robin.Maley@sedgwick.com

Mike Midgley, RN JD MPH CPHRM FASHRM DFASHRM
VP, Healthcare Risk Engineering
Swiss Re Corporate Solutions
mike_midgley@swissre.com

Jonathan D. Rubin, Esq.
Partner
Kaufman Borgeest & Ryan, LLP
jrubin@kbrlaw.com

Alvin Safran
Chair, AHRMNY Membership Committee
Risk/Claims Management Consultant
asafran@aol.com

Margaret Sullivan, RN CRM
Regional Risk Manager
Advantage Care Physicians
sullivanm@acpny.com

Francine Thomas, RN BSN MA CPHRM FASHRM
Risk Manager
Hudson Insurance Group
fthomasft0@gmail.com

Carolyn Reinach Wolf, Esq.
Executive Partner
Abrams Fensterman Fensterman Eisman Formato Ferrara & Wolf, LLP
cwolf@abramslaw.com



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AHRMNY
PO Box 4200, Grand Central Station
New York, NY 10163

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