AHRMNY
The Association for Healthcare Risk Management of New York, Inc.

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PRESIDENT'S MESSAGE

Dear Members:

Great news! The Association has officially launched the redesign of its website. The chairpersons of the Public Relations committee and the committee members continue to work diligently toward the future phases of the revision. We have made a strong commitment toward this project as we strive to customize, update and shift toward a more user friendly version. As efforts continue with this revision, the official launch of our website is exciting and welcomed news.

On the heels of our December half day conference; we experienced a successful webinar on February 12, 2014 on the topic of Patients and Families as Safety Partners by Ronette Wiley, RN, MHA, BSN, CPPS, Vice President of Performance Improvement and Care Coordination, as well as Chief Compliance Officer at Bassett Medical Center. Ms. Wiley shared how the concept of partnership is an essential component for a healthcare culture that supports patient safety, patient satisfaction and successful outcomes in the clinical setting. Over 75 people attended the webinar and we plan to continue to use this media as a means to extend educational opportunities to our members.

Many thanks, to Wilson, Elser, Moskowitz, Edelman and Dicker, LLP for their sponsorship of our March 2014 Education and Networking event which will be held at the Lighthouse International. Kathleen Shure, SVP of Greater New York Hospital Association, presented on the topic of Health Exchange Implementation: How it will impact Hospitals and Risk Managers. The presentation was truly informative and dynamic as it revealed the impact of the health exchange on the insurance markets, hospital operations, risk managers and the consumers of health care. This topic continues to be of great interest to healthcare entities in light of the Affordable Care Act.

The annual full day conference will return to the Lighthouse International on Friday June 6, 2014. We invite you to save the date. We will keep you posted on that day's topics as soon as they are finalized; however, in the initial planning stage is the topic of future issues facing hospitals and healthcare systems as well as individual providers. We also plan to continue with breakout sessions for attendees. As always, we would also like to thank the continued generosity of our sponsors and exhibitors.

It is that time of year again as the Nominating Committee has begun to initiate the process to propose members for the vacancies in the positions of Board Officers and Directors, and getting the ballots out to our members to vote. We ask that you consider nominating those who you believe will truly serve the organization. The deadline for submission of nominations is March 31, 2014.

As always, we are appreciative for our generous sponsors without whom; these events and opportunities would not be possible. Their support is essential to our organization.

Our Fundraising Committee continues to reach out for sponsors to support our programs. In efforts to promote advertising and other fundraising ventures, the chairpersons of the Fundraising and Publications committees have formed a task-force to develop a platform for advertising in the Risk Management Quarterly (RMQ.) *We invite those in the business of healthcare to expose your business to our readership*.

In conclusion, the Publications Committee has produced another outstanding publication and they continue to raise the bar for the RMQ. I hope you enjoy this edition of the Risk Management Quarterly with thought-provoking, topical and useful information.

Regards,

Francine

Francine A. Thomas, President
July 1, 2013-June 30, 2014

EDITOR'S CORNER

The Risk Management Quarterly (RMQ), the official journal of the Association for Healthcare Risk Management of New York, Inc. is published four 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 regulations, 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.

For the official ***RMQ*** Author Guidelines visit our website http://www.ahrmny.com

Reminder:

Maximum article length 3,500 words

Photo requirements: (high resolution JPEGs – at least 300 dpi)

AHRMNY will not publish those articles promoting products or services

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WE WANT TO HEAR FROM YOU FOR THE SPRING AND SUMMER EDITIONS

We are asking our readers to submit articles for the spring and summer 2014 editions of the ***RMQ*** that focus on patient safety, environmental or staff safety, risk management, claims management, insurance issues and other relevant topics.

RMQ is published four times a year with a distribution of approximately 300 copies per quarter. Please forward any ideas or submissions for publication in the ***RMQ*** to "**Editors**", via email with attachments to: ahrm@optimum.net

The deadline for submission and consideration for the next journal is **May 1, 2014**.

Upcoming Educational Programs

SHCRM•NJ Society for Health Care Risk Management of NJ

Friday-March 28, 2013 at the Princeton Insurance Company

Disclosure, Apology and Early Resolution: A Risk and Claims Primer

Visit http://www.shcrmnj.org/index.php?pgid=meetings **for program brochure and registration.**



The 16th Annual NPSF Patient Safety Congress Is Headed to Orlando

Join us May 14-16, 2014, for the only global meeting with a singular focus on patient safety.

Click link below to download program brochure and register for the event: http://npsfcongress.org/wp-content/uploads/2014/01/NPSF_Congress2014_PrelimProgram_web.pdf

AHRMNY

SAVE THE DATE

Friday, June 6, 2014
8:30 AM – 3:30 PM

AHRMNY ANNUAL CONFERENCE
Lighthouse International, NYC

Program brochure and registration details coming soon to www.ahrmny.com

WHERE ARE WE ON OUR JOURNEY TO IMPLEMENTING A "SAFE CULTURE"?

By Joyce Lagnese, JD; Heather Marchegiani, BS; Cheryl DeSimone, BA

Over the past several years, hospitals around the country have been implementing checklists, protocols, time outs, etc., all in an effort to improve patient safety and mitigate harm caused by preventable errors. However, data suggests that many of these efforts are not having as significant an impact as initially hoped. Instead, it is becoming clear that hospitals and healthcare organizations need a change in their underlying culture. The below case study depicts the impact a culture change could have had on saving a patient's life. While this case was almost 15 years ago, could this event still happen today?

Case Study: The Lewis Blackman Story (http://www.lewisblackman.net/)

Lewis Blackman was a 15-year-old boy suffering from pectus excavatum. His parents debated over allowing him to have the corrective operation for years, always deciding it was too extensive and invasive. In 1999, they saw an article about a new operation that was supposed to be safer and quicker. The surgery would be performed in an hour through two small incisions. Given this new surgery, Lewis and his parents consented to the procedure.

On Thursday, November 2nd, 2002, Lewis was admitted for surgery. The surgery was supposed to last only one hour, but instead, it took two and a half hours. The surgeon noted in the record that he had to reposition the metal bar several times, but the surgery was eventually successful. Lewis' initial recovery in the PACU was noted to be uneventful. However, doctors and nurses noted in the record that he wasn't producing any urine. He was given Toradol for pain, and described his pain in the PACU as a "three" on a scale of one to 10.

On 9 am on Saturday, the covering attending surgeon checked on Lewis and documented, "No evidence of infection. Clear lungs. May sit up and consider getting out of bed." This surgeon was the last attending provider to see Lewis for two days.

By 6:30 AM on Sunday, Lewis complained of pain in his upper abdomen and described it as a "five on a scale of one to five." The nurse told Lewis and his mother that it was gas. Her notes indicate, "gas pains…pt needs to move around." Another nurse suggested a bath, so she and his mother put him in the tub and sponged him off.

Throughout the afternoon on Sunday, the mother called the nurse a number of times and indicated in her diary that the nurse "seemed convinced that Lewis was simply lazy and not walking enough to dissipate his 'gas pain'." The mother repeatedly asked for an attending physician and instead, Lewis was visited by a first year resident. The mother demanded to have her son examined by an attending, and her insistence was documented in the record at 6:26 pm – "parent requested upper level MD."

At 8 pm on Sunday, the Chief Resident visited Lewis and documented "probable ileus" and ordered a suppository. The Chief Resident also indicated that Lewis' heart rate was "slightly above normal", however a nurse's note written at the same time indicated a heart rate of 126 and that he was sweating.

On Sunday night, Lewis' heart rate was 142 and his temp was 95. By Monday morning, Lewis was visited by a new resident who told his mother that his pale color was a result of low blood pressure. Records indicate that from 8:30 to 10:15 am, they were unable to detect a BP at all. The residents believed that the blood pressure devices were broken and focused entirely on the equipment.

By noon on Monday, two technicians arrived for a blood draw, and could only get a small amount of blood. As this was happening, Lewis told his mother, "it's going black." The mother called for help and the Chief Resident arrived, at which time he called a code. Despite resuscitation efforts for 60 minutes, Lewis was pronounced dead at 1:23 pm. At 2:00 pm, the Code Leader documented, "it is unclear why the patient expired at this time. We will pursue an autopsy." An autopsy later revealed that Lewis died of a perforated ulcer and his abdomen was filled with almost three liters of blood.

Reflecting on this case, there are several questions that can be raised about the care provided to Lewis:

1. Where was the critical thinking? For example, why were the residents so focused on equipment issues when trying to determine Lewis' BP?
2. Why didn't the residents or nurses seek guidance from an attending physician? Why wasn't an attending physician called over the weekend, particularly after the mother made the request?
3. Did the providers and nurses have a "habit of mind" that this is a painful surgery and Lewis needed to "suck it up"?
4. Did the providers and nurses view the mother as "overprotective", and therefore, fail to carefully consider her concerns?

Since the publication of "To Err is Human" by the Institute of Medicine in 1999, much attention has been placed on improving patient care and reducing preventable harm. This report published shocking data, indicating that as many as 98,000 patients die each year in hospitals as a

result of a preventable medical error, and that these errors are costing at least $17 billion each year (http://www.iom.edu/~/media/Files/Report%20Files/1999/To-Err-is-Human/ To%20Err%20is%20Human%201999%20%20report%20brief.pdf). Since the publication of this report, the general public has become intolerant of medical errors, and an intense focus has been placed on mitigating preventable harm.

Lucian Leape, a pioneer in the patient safety movement, said "The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes." For a long time, hospitals and physician groups focused on individual blame. When something went wrong, the organization would focus on who was to blame, and then punish them. In fact, Medscape published an article in 2007 indicating that only 10% of medical errors were the result of a specific individual, and 90% of errors were a convergence of factors where there were multiple opportunities to prevent harm (http://www.medscape.org/viewarticle/550273).

To truly have an impact on patient care, organizations must change their "institutional culture", or the sum of assumptions, beliefs, and values that its members share and express through behaviors. This requires:

1. Changing underlying assumptions, behaviors, and processes;
2. Promoting intentional focus, time, and patience for all tasks related to patients; and
3. Fostering deep and pervasive commitment to patient safety.

By implementing a "culture of safety", caregivers become invested in improved patient care. It requires "buy in" at all levels of the organization, including leadership, middle management, and front line staff. A "culture of safety" can be characterized by the following 10 qualities:

1. The culture is centered on teamwork, grounded in a mission and purpose of vigilance, and continually alert to threats to patient safety.
2. Every voice is heard, and every worker is empowered to speak up to prevent system breakdowns.
3. Every team member is equal with respect to patient safety. There can be no hierarchies when a patient's safety is concerned.
4. Patients and families are respected and considered an integral part of the care team, and made fully engaged in their care.
5. Learning is revered, promoted, and rewarded.
6. There is psychological safety for everyone to confront everyone else for the best interests of the patient.
7. There is a sense that safety and quality are expected and rewarded.
8. There is a sense of urgency to resolve issues, including changing current behaviors and processes to mitigate harm.
9. Where "shame and blame" are eliminated, but accountability is still present.
10. Where no one is an "employee", but everyone is a "caregiver."

None of these can be accomplished without teamwork and communication. Extensive research has been done on the effectiveness of teams, finding that to employ a successful and effective team, the "Five C's" must be deployed:

1. Teams must have a Common Goal. They must share an understanding of the short- and long-term goals, work together to achieve them.
2. Teams must share Commitment. Every team member must be committed to attaining the goals, and be willing to sacrifice their individual goals to achieve the team goal.
3. Teams must be Competent. Every team member must have the knowledge, skills, behaviors, and attitudes necessary to successfully accomplish their role in the team's activities.
4. Teams must Communicate. All team members must communicate effectively and efficiently with one another and the patient.
5. And, teams must be Coordinated. Resources, technology, and people must be coordinated effectively.

The following case study demonstrates the improved outcomes that result from a culture of safety that seeks to reward care providers for catching "near misses".

Case Study: The Incidental Finding

A 51-year-old female with a history of hypertension, asthma, diabetes, and a 20-year, pack-a-day smoking history presented to her PCP on September 17, 2007 with complaints of severe and sudden onset of abdominal pain. The patient was sent to the ED, where she was seen by a surgeon, who ordered diagnostic studies, including an abdominal study and a chest x-ray. The initial report on both of these studies came back "negative". The patient was admitted to the hospitalist service for further evaluation of her abdominal pain.

The surgical evaluation identified an acute abdomen. The patient was emergently taken to the OR, where she was diagnosed with a ruptured appendix and peritonitis.

The final x-ray report was dictated by the radiologist several hours after the appendectomy was performed. The x-ray findings included, "… a questionable prominence of the right hilum. If previous studies are available, this would allow for further evaluation. In lieu of this, a follow-up study in perhaps one month is suggested." This report was sent to the attending physician (surgeon), the ordering physician (ED physician), and "other

location" (patient's primary care physician). The patient was discharged home on September 26, 2007. Because the final chest x-ray report was not sent to the hospitalist service, there was no notation in the discharge summary of the abnormality or recommended follow up.

On October 2nd, 2007, the patient presented to the surgeon's office for a post-operative checkup. In preparation for the patient's visit, the surgeon's nurse reviewed all recent records and noted the abnormality in the chest x-ray report. She noticed that the surgeon had not seen the report as his sign-off was not there. She relayed the concerns to the surgeon, and recommended that someone get in contact with the PCP. The surgeon admitted that he missed the report and agreed with the nurse's recommendation. The nurse contacted the PCP, and the surgeon reviewed the results with the patient and noted that the PCP was also aware and would be contacting the patient to schedule follow up studies.

The patient was ultimately diagnosed with Stage II lung cancer and underwent immediate radiation therapy and chemotherapy. Without the nurse's involvement, this cancer could have gone undiagnosed and resulted in further advancement of the disease.

A true "culture of safety" is achievable and is imperative in mitigating harm. Imagine a culture where acceptance of the reality of human error leads us to openly ask and rely upon our team members to preempt us when they perceive we may be on a path to a mistake. Imagine a culture where we want to sacrifice our ego to expose our own "near misses" because we know that is the catalyst for improved safety. Imagine a culture where we want to expose the "near misses" of others and we want others to expose their observed "near misses" of us. And, imagine a culture where it is psychologically safe to do this, and furthermore, where it is rewarded and not punished. That will be the day when care is truly "patient centered."

About the authors



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Cheryl DeSimone, BA: *Director of Sales and Business Development* – Ms. DeSimone has over 25 years of marketing experience with a concentration in healthcare. After detailing specialty products to physicians and pharmacists for years, Ms. DeSimone worked as a Publication Director at a medical publisher before accepting the position of Managing Director of Marketing at The New York Time. At The Times, she spent the majority of her 13 years focused on marketing and business development with hospitals and healthcare organizations. Ms. DeSimone received her degree in Journalism and Mass Communications from New York University.

SPECIAL ANNOUNCEMENT



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THE PATIENTS NO ONE WANTS: ADDRESSING OUR NATION'S MENTAL HEALTH CRISIS

By Samantha E. Quinn and Richard W. Nicholson

Introduction

Just type the words "Mental, "Health," "Treatment," and "Crisis" into your internet search engine and scan the results. After a matter of seconds, it will become clear that the apparent deficiencies of the U.S.'s mental health system are a hot topic among the media, medical professionals, and pretty much everyone else. What will be less clear, however, is what policy-makers should do about this crisis. While most advocates agree that the government is not allocating sufficient funds to mental health treatment facilities, be it due to the economy or ideology, how those precious dollars should be spent and what programs should get the green light remains a hotly contested issue. Further, when governmental mental health programs come up short, the burden falls on patients and their families, and at times, the community at large. Whether it be money, time, or safety, the costs of mental health treatment have become increasingly difficult to bear.

The difficult economic times of the "Great Recession" have further exacerbated this crisis. The National Alliance on Mental Illness ("NAMI") estimates that states, whose roles in mental health treatment are more significant compared to physical health, have cut more than $1.6 billion from their mental health budgets over the recession.[1] For example, the state of California reduced mental health spending by $764.8 million, New York by $204.9 million, Illinois by $187 million, Massachusetts by $55.6 million, and Ohio by $26 million.[2] NAMI also rated each state for their delivery of mental health care, and while the US received a deplorable "D" overall grade, individually New York and Massachusetts received a "B," California and Ohio a "C," and Illinois a "D."[3] Sadly, not one state earned an "A" rating.[4] What is most alarming is that these budget cuts have not been limited to the worst performing states, and states like Massachusetts and New York whose "B" ratings are two of the few bright spots in NAMI report, have also slashed their already insufficient budgets. 4,000 psychiatric hospital beds have been eliminated since 2010, and spending cuts have shifted costs of long term care to systems responsible for responding to psychiatric emergencies such as ERs, police and homeless shelters, thus placing an undue burden on those systems.[5]

While the recent budget cuts may only be a temporary response to unprecedented economic turmoil, the largest cuts which have targeted state-run psychiatric hospitals reflect a decades-old policy shift.[6] Thus, to understand the future of mental health treatment in this country we will need to look to the past. Over the last fifty years, the United States has engaged in one of the largest social experiments ever attempted by the U.S. government.[7] The move away from state-run mental health institutions to community based treatment facilities has resulted in the transfer of hundreds of thousands, perhaps millions, of mentally ill people from inpatient facilities to local communities.[8] The impact of this process, which is known as deinstitutionalization, has been far-reaching.[9] Some argue that deinstitutionalization, while imperfectly implemented by the government, has improved the quality of life for patients. Others point to the exploding prison and homeless populations, and argue that we have just moved patients from one type of isolation to another.

After giving a background on the history of deinstitutionalization, this article will look to the legal debate that has accompanied it, and will then focus on a specific legal proceeding, the Assisted Outpatient Treatment Order (AOT), which has been created to mitigate some of the problems caused by deinstitutionalization.

Deinstitutionalization

Deinstitutionalization was not the result of one giant decision, but the collection of several decisions by federal and state agencies to move away from the large state-run mental hospitals which predominated since the second half of the 19th Century. This process began in the 1950s, in the wake of several scandals about the deplorable conditions of many state-run mental institutions, and has continued until today.[10] To put things in perspective, in 1955 there were 558,239 patients living in state psychiatric hospitals. In 1994 there were 71,619 patients.[11] Taking into account the explosive growth of the United State population over the 40 years between 1955 and 1994, nearly 100 million people, the ultimate effect of deinstitutionalization was that 92% of the patients who would have been living in state mental hospitals in 1955 were not living in them in 1994.[12] Where these patients went is a matter of intense debate between those who champion deinstitutionalization and those who think it went too far.

The goal of deinstitutionalization was to send mental health patients into community located, outpatient treatment centers so that they could be integrated into the community with as little infringement upon their rights as possible.[13] In 1963, President Kennedy launched one of the first federal initiatives at deinstitutionalization, by launching the Community Mental Health Center program.[14] This program sought to replace overcrowded and restrictive mental health institutions with smaller outpatient facilities more tied to the community. This initiative was expanded through the 1970s, including a vast increase in the amount of services covered by Medicare

and Medicaid, as well as increased income support through Supplemental Income Security ("SSI") and Social Security Disability Insurance ("SSDI").[15] These major shifts, coupled with state level reform, have resulted in what could be considered the nominal goal of deinstitutionalization—fewer patients in over-crowded and restrictive state mental institutions. Yet, even the staunchest advocates of deinstitutionalization would concede that it has been a haphazard and imperfect process, which has often left both patients and families in incredibly difficult positions. Too often, patients were sent to facilities ill-equipped with the resources to handle long term mental healthcare or lacking the mental health professions to handle difficult mental illnesses.[16] Politics also played a role when funding was easily cut and baseline targets, namely reduction of state hospital beds, were championed over quality of life improvements.[17] Ultimately, deinstitutionalization advocates would probably admit there is a long way to go until community focused healthcare becomes what they hope it can be, but they still believe that, on the whole, deinstitutionalization has been a net good for those afflicted with mental illnesses in this country.

Critics of deinstitutionalization tell a much different story, however. They argue that while deinstitutionalization may have worked for many, maybe the majority of people housed in state run mental institutions, that a substantial minority of the most at-risk, severely mentally ill people were cut loose. Worse yet, not only were they subjected to lack of treatment or homelessness,[1] some argue that the seriously mentally ill traded one type of isolation for another: prison. Between 1980 and 1995, the total number of individuals incarcerated in American jails jumped from about 500,000 to nearly 1.6 million, an increase of 216%.[19] The U.S. population only increased 16% over that time period.[20] While much of this increase was associated with changing demographics, the drug war, and more stringent sentencing guidelines, critics argue that deinstitutionalization was a significant factor as well.[21] Scholars have actually named this phenomenon the "balloon theory," and argue that, similar to what occurs when squeezing a balloon, when either the supply of mental institutions or prisons is constricted, the mentally ill will flood the non-constricted institution.[22] An example of this phenomenon, is described a 1992 Public Citizen survey that found "that *29 percent* of the jails sometimes incarcerate persons *who have no charges against them* but are merely waiting for psychiatric evaluation, the availability of a psychiatric hospital bed, or transportation to a psychiatric hospital."[23] Mercy bookings, the practice of arresting the homeless mentally ill who refuse treatment or medication so that they have a safe place to sleep, is another example.[24]

The overall demographic numbers show the increase of the mentally ill in jails and prisons as well. In a 2004 survey, the Department of Justice found that roughly 56.2% of state prison inmates, 44.8% of federal prison inmates, and 64.2% of local jail inmates had been treated for a mental health problem within a 12 month period.[25] Taking a look at serious mental illness, a 1983 study found that about 6.4% of inmates suffered schizophrenia, schizophrenia spectrum disorder, schizoaffective disorder, bipolar disorder, brief psychotic disorder, and delusional disorder.[26] A 2009 study found that number to be 16%.[27] Further, as of 2005, the odds of a seriously mentally ill person being in jail or state mental institution, was 3.2 to 1.[28] This means that there were three times as many individuals with serious mental illness in jails as compared to state mental institutions. Also, a NAMI study found that about 40% of the mentally ill had been in jail at some point in their lives.[29]

Sadly, America's jails have become our new mental hospitals, and it is clear that mentally ill inmates are not receiving the care they need. In Massachusetts, prison suicides are at a crisis level and in Maine, nearly half the people incarcerated suffer from mental illness and are not receiving adequate mental healthcare.[30] This unfortunate result of the dwindling availability of inpatient treatment options due to deinstitutionalization is one of the most critical aspects of our nation's mental health crisis which needs to be addressed.

The Mental Health Treatment Debate Today

While the medical efficacy of deinstitutionalization has been much debated over the last 50 years, and will continue to be, the remainder of this article will instead focus on its legal foundations. The champions of deinstitutionalization base their beliefs on patient self-determination. These groups, chief among them the Bazelon Center for Mental Health Law,[31] believe that any kind of involuntary treatment program, absent emergency, is a massive curtailment of rights.[32] They point to Supreme Court precedent that holds that involuntary inpatient commitment must be accompanied with due process of law,[33] as support for their contentions. Further, they believe that all involuntary *outpatient* commitments are an infringement of an individual's constitutional rights.[34] They believe that most involuntary outpatient commitment programs lack the necessary criteria to satisfy basic due process standards, and fail under the "imminent, significant physical harm" standard set out by the Supreme Court.[35] They believe, "the vast majority of individuals with mental illnesses are better served by access to appropriate voluntary services in the community."[36] Ultimately, they believe that hard-earned patient civil rights and new-found community reintegration need to be protected from the encroachment of involuntary treatments regimes that would curtail the progress of deinstitutionalization out of expedience rather than emergency.

Those on the other side of the debate agree that voluntary treatment is preferable to involuntary treatment. But, unlike their less realistic counterparts, they argue that

exclusively voluntary treatment options are insufficient to deal with the exploding number of people with serious mental illness. Groups like the Treatment Advocacy Center[37] base their beliefs on two arguments. First, they argue that most mental illness, particularly schizophrenia and bipolar disorder, are biologically based diseases that attack the brain[38]. They argue that these mental illnesses render people incapable of voluntarily entering treatment because they are unable to make rational decisions or are unaware they are ill[39]. They call this condition Anosognosia[40]. While its clinical existence is still being investigated and debated by the medical community,[41] anecdotally the concept of Anosognosia has validity. A 2001 study surveyed individual with severe psychiatric disorders, and the single most common answer, at 55% of those polled, for why they did not take their medicine was that they did not believe they were sick[42]. Second, the Treatment Advocacy Center argues that consequences of untreated mental illness are so grave—homelessness, criminalization, suicide, violence, victimization, and unnecessary suffering—that allowing severely ill patients alone to make treatment decisions can be both devastating to the patient and society at large[43]. Their beliefs can be summed up as: "The opposition to involuntary committal and treatment betrays a profound misunderstanding of the principal of civil liberties. Medication can free victims from their illness—free them from the Bastille of their psychoses—and restore their dignity, their free will and the meaningful exercise of their liberties."[44]

Kendra's Law and the AOT

To make matters more complicated, tragedy has a way of taking this debate from the back burner to the front page. With the Newtown, Connecticut mass shooting still fresh in many people's minds, states, most notably New York, have begun to enact controversial new laws aimed at keeping firearms from mentally ill people. The shock and horror and the corresponding action comes as no surprise. It is a natural human reaction: one that has replayed itself many times before.

There was another tragedy, over a decade old at this point, and another law passed in response to it. In January 1999, Kendra Webdale was pushed off a New York City subway platform and killed by an oncoming train.[45] Andrew Goldstein, a 29-year-old man with a long history of mental illness and of non-compliance with medication, was the perpetrator.[46] The result of this tragedy was a campaign and resulting legislation that created a framework for court-ordered assisted outpatient treatment ("AOT"). The law, which was signed by Governor Pataki in 1999 and has been extended by the legislature until 2015,[47] stated that there were "mentally ill persons who can function well and safely in the community with supervision and treatment, but who without such assistance, will relapse and require long periods of hospitalization," The purpose of the AOT "is compassionate, not punitive, [and] will restore patients' dignity, and will enable mentally ill persons to lead more productive and satisfying lives."[48] Moreover, since the public's association of mental illness with violence is likely the major cause of stigma against people with mental illness, the most effective way to decrease this stigma is to reduce the incidence of violent crimes. Violence is associated only with *untreated* mental illness. Therefore, ensuring that those who need treatment actually get it is another essential step in the process of addressing our nation's mental health crisis.[49]

The AOT in Practice

The AOT process begins when a family member or a person empowered by statute files a petition in the supreme or county court in which the subject of the petition is present or reasonably believed to be present.[50] The criteria for an AOT are as follows: (1) is eighteen years of age or older; (2) is suffering from a mental illness; (3) is unlikely to survive safely in the community without supervision, based on a clinical determination; (4) has a history of lack of compliance with treatment for mental illness; (5) is unlikely to participate in outpatient treatment; (6) is in need of assisted outpatient treatment in order to prevent a relapse or deterioration which would be likely to result in serious harm to the person or others; and (7) is likely to benefit from assisted outpatient treatment.[51] The fourth criterion, lack of compliance with treatment, has two conditions which must be satisfied. First is at least two hospitalizations for mental illness, as a result of treatment failures, within the last thirty-six months. The second is that there must be one or more acts of serious violent behavior toward self or others or threats of, or attempts at, serious physical harm to self or others within the last forty-eight months.

In addition to stating facts that support the contention that the subject meets the criteria for an AOT, the petition must include an affidavit by a physician who personally examined the subject no more than ten days prior to filing,[52] as well as a written treatment plan. The plan must be prepared by the physician and should include all medication to be prescribed, therapy options, educational or vocational training possibilities, and whether petitioner would benefit from alcohol or substance abuse treatment.[53] The examining physician must allow the subject the opportunity to actively participate in the development of the plan.[54]

Upon receipt of an AOT petition, the court must schedule a hearing no later than 3 days from the date of receipt.[55] The physician who either recommended the AOT (physicians are empowered to do so by the statute) or who conducted the physical examination, must testify in person at the hearing, as to satisfaction of the AOT criteria and the efficacy of the written treatment plan.[56] After the hearing, if the court finds by clear and convincing evidence that the subject of the petition meets the criteria for an AOT, and there is no appropriate or feasible alternative, the court may order the

subject to receive AOT for an initial period not to exceed six months.[57] A court order for AOT may also be appealed. In addition, assisted outpatient, the Mental Hygiene Legal Services advocate, or anyone acting on behalf of the individual may petition the court to stay, vacate, or modify the order.[58]

The AOT under Scrutiny

When it was passed in 1999, New York's AOT program was the first of its kind. Since its inception, the law has been challenged on both legal and empirical grounds. To date the law has withstood this scrutiny.

Soon after passage, the constitutionality of Kendra's Law was challenged and was upheld by the New York Court of Appeals. In *In the Matter of K.L.*, the appellant argued that the AOT procedure did not provide due process of law because it does not require a finding of incapacity before ordering compliance with the AOT.[59] The Court of Appeals held otherwise, noting that the AOT procedure does not compel forced medical treatment because the patient is given the opportunity to help develop and control the nature of his or her treatment.[60] Further the court held that the state was justified in minimally restricting the right to refuse treatment because of its general police powers to protect the public from harm and also its *parens patriae* power to provide care to citizens unable to care for themselves because of mental illness.[61] In 2010, a federal Fourteenth Amendment due process challenge to the AOT program was upheld by the S.D.N.Y.[62] In denying the claim, the court highlighted the amount of medical input required, the availability of hearing with a jury, ability to appeal, and the legal representation provided by Mental Hygiene Legal Services as adequate due process protections.[63]

Starting in 1999, several studies have been conducted testing the efficacy of the AOT. While further research is required, the initial feedback of these studies has been positive. A 2010 paper found that among individuals who received an AOT between 1999 and 2007, inpatient hospital admissions were reduced by 25% in the initial 6 month AOT period, and were reduced by almost 40% if the AOT order was renewed.[64] A companion study found that patients in an AOT programs had higher medication possession rates, even after the AOT period had ended.[65] Finally, another 2010 study found that incarceration rates among AOT recipients decreased while enrolled in the program.[66] Critics of the AOT will point to an incredible 97% rate of granting AOT petitions, as well as 61% rate of renewal, as a symptom of a system stacked against the subjects of the AOT.[67] With numbers that high, there could be truth to that assertion. Yet, the apparent success of the program, lower hospitalization and incarceration rates and higher medication possession, may temper some of those concerns.

Conclusion

Despite the fact that New York State has one of the nation's highest rated healthcare systems, New York's mental health resources are still woefully lacking; there is an acute shortage of both psychiatric hospital beds and resources to respond to acute mental health emergencies. One positive step that New York has taken, however, is the implementation of the Assisted Outpatient Treatment system. Putting aside ethical and philosophical disagreement over the efficacy of Kendra's Law in advancing treatment of the mentally ill, from a pragmatic point of view, the AOT system, while not perfect, is working. The people intimately involved in the struggle against mental illness - the patients, families and mental health professionals - are necessarily focused on practicality. Although protecting the civil liberties of all citizens is a priority, we cannot lose sight of the need to help the victims of mental illness move towards full participation in society. The AOT system is an essential step in that process and in addressing the nation's mental healthcare crisis.

References Listed on page 32

About the authors

Samantha E. Quinn and Richard W. Nicholson are partners in the firm of Schiavetti, Corgan, DiEdwards, Weinberg & Nicholson, LLP which specializes in the defense of hospitals, doctors and other health care providers. Special thanks to Richard W. Nicholson for his contribution to this article.

Fall Conference Summary
Friday, December 6, 2013
Beth Israel Medical Center

Despite the brutal cold, AHRMNY's December 2013 Half Day Conference proved to be quite a success with over 80 members and guests in attendance. Convened at Beth Israel Medical Center's Bernstein Pavilion, the Education Committee coordinated two dynamic programs for the day.

Robert Gibson, Esq. and Jesse Capell, Esq. from the firm of Heidell, Pittoni, Murphy and Bach started the day with an informative and comical review of social media use at jury trials. Using actual social media posts as examples, Misters Gibson and Capell not only reviewed the ethical implications of conducting internet research on prospective jurors, but also reviewed the issues that can arise of internet use by jury members during a trial.

Our second speaker, Laurie Cohen, Esq. from the firm of Nixon Peabody traveled all the way from Albany to address the group on an enterprise risk management approach to pay for performance initiatives with respect to patient satisfaction. Since pay for performance is not typically in the forefront of day to day risk managers, the topic was very well received by the attendees.

The Half Day Conference ended with some brief networking while attendees enjoyed some hot coffee and refreshments before heading back out to the elements of winter. AHRMNY would like to pay special thanks again to Beth Israel Medical Center for their hospitality and support throughout the day.

member SPOTLIGHT

The Certified Professional in Healthcare Risk Management (CPHRM) designation is a testament to risk management's dedication to patient safety. As you know, it takes a commitment to reach this goal and the AHRMNY Board of Directors would like to congratulate several of our members who have traveled unique roads to reach this honorable achievement.

Introducing our new CPHRM Recipients…….



Naeem Vakil Holmes, CPHRM

Naeem has had a varied career and experiences. She began her career as a journalist for a city magazine in India. She also worked with rural women's development programs for Save the Children in Bangladesh. She graduated with a Bachelor's degree in Nursing from Hunter College in New York City and worked as an RN at New York University Medical Center in NYC. Naeem has a JD from Fordham University School of Law in NYC. Naaem has experience in medical malpractice defense litigation as well as claims management.

Naeem is currently the Director of Risk Management at New York Methodist Hospital in Brooklyn, New York. She earned her Certified Professional in Healthcare Risk Management designation in October 2013.



Teri Reinhartsen, RN MS CPHRM

Teri is a Patient Safety/Risk Manager at New York University Medical Center. She obtained degrees in Nursing, Legal Studies with certificates in LNC and Paralegal, and a Master's in Healthcare Management. Her nursing experience covers utilization review, employee health, home care, operating room and nursing lab instructor. Teri credits her mentor Alan Lieber, Esq. in helping her begin a career in Risk Management while working for Barnett, Edelstein, Gross, Kass & Lieber.

Teri earned her Certified Professional in Healthcare Risk Management designation in September 2013.



Linda Tallaksen, PA-C, MSA, CPHRM

Linda is a Regional Risk Manager and Physician Assistant in urgent care at AdvantageCare Physicians. AvantageCare Physicians is one of the largest multi-specialty physician practices in the New York metropolitan region offering an expansive complement of primary and specialty care services. Linda has been able to combine her clinical experience as a physician assistant and her administrative skills and knowledge of insurance in order to manage risk and promote quality and safety for the Brooklyn regional offices.

Linda earned her Certified Professional in Healthcare Risk Management designation in August 2013.

Francisco Rivera, CPHRM



Francisco A. Rivera "Frank" is a Patient Safety & Risk Manager at NYU Langone Medical Center. He has held this position since 2011, prior to joining NYULMC he worked at Memorial Sloan Kettering Cancer Center as a Registered Nurse in a variety of settings. After being honorably discharged from the US ARMY, Frank received his BSN from Hunter College and earned an MS in Health Policy and Management from The New School. Frank is an avid runner currently residing in New Jersey.

Frank earned his Certified Professional in Healthcare Risk Management designation in March 2013.

Rosemarie White, BSN, RN, CPHRM



Rosemarie is the Director of Risk Management & Quality Assurance at Mount Kisco Medical Group, P.C. a large multi-specialty physician group located in Westchester, Putnam and Dutchess counties. Previous to this position she worked for the University of Medicine and Dentistry of New Jersey (UMDNJ) in the Risk & Claims Management Department for 15 years.

Rosemarie earned her Certified Professional in Healthcare Risk Management designation in March 2013.

Sabrina Madden, CPHRM



Sabrina currently serves as the Director of Risk Management for Samaritan Health in Watertown, NY, overseeing claims management and insurance for a 294-bed not-for-profit community medical center, a 288-bed skilled nursing and assisted living facility, and a 272-bed long term care facility. Sabrina received her start in risk management at the US Army MEDDAC at Fort Drum, NY. Previous to her risk management career, Sabrina was a police officer in the US Army and a social worker.

Sabrina earned her Certified Professional in Healthcare Risk Management designation in June 2012.

Lesli Giglio RN, MPA CPHRM



Lesli has 25 years of experience in the field of Risk Management, Claims Management and Patient Safety. She began her career at FOJP Service Corporation and held positions at North Shore-LIJ Health System and most recently as the Director of Risk Management, Regulatory Affairs, Privacy/Patient Safety Officer at St. Francis Hospital. Lesli received her MPA from CW Post in 1999 and received the Phi Alpha Alpha award for excellence.

Lesli earned her Certified Professional in Healthcare Risk Management designation in February 2012.

ICD-10 CM/PCS:
IMPACT AND OPPORTUNITIES FOR RISK MANAGEMENT

By Sandra Phillips Sperry

On October 2014 health information management systems will convert to ICD-10 CM/PCS. Implementation marks more than 10 years of development and discussion of the opportunities and threats projected to the processes of health care. Both the professional literature and public press have posed conflicting and provocative views that range from the solution to managing risk effectively to the demise of one out of five health care organizations. The emphasis in these discussions is on projected transition costs, clinical documentation, provider productivity and decreased reimbursement. Risk management issues are framed in the context of mitigating error, system failures, and impact of diminished productivity of hospital information and revenue cycle staff.

The significance of mitigating risk outside of the revenue cycle sphere is gaining recognition as organizations begin to understand that the ICD-10 conversion will affect many processes and outcomes. The greater granularity and specificity of ICD-10 will add robust detail to clinical information not previous accessible and will be a major variable in driving future risk forecasting, prevention and management.

Historical Overview:

The International Classification of Diseases (ICD) was established by the World Health Organization (WHO) as the standard for documentation in epidemiology and health management. The system provides a data base for archiving and analysis of health information for population groups and subsets. The initial intent of building a classification system was to delineate the incidence and prevalence of diseases and other health problems apply this rich data source to decision making. Over time many countries have applied the data to determine reimbursement methodologies and improve resource allocation. ICD-10 was endorsed by the Forty-third World Health Assembly in May 1990 and came into use in WHO Member States in 1994. (WHO, 2013).

That same year the National Center for Health Statistics (NCHS) was established in the U.S. to consider the issues around adoption and modification of ICD-10. Numerous clinical modifications were ultimately added to the ICD-10 CM classifications as well as the development of a procedure classification system (PCS) version for procedures. PCS is a robust system that includes greater anatomical and procedural detail than the historical CPT coding system. The political environment around health care reform and the large number of constituencies affected by the new system resulted in the ICD-10 CM/PCS planning and development encompassing a long and volatile process of appeal and postponement. The system is currently set to be in full implementation by October 1, 2014. (DeVault, Barta, Endicott, 2013)

In light of the linkage between reimbursement and coding language, ICD-10 is frequently and exclusively viewed as a revenue cycle issue. In fact, the classification system is the new clinical "language" of health care management. The ICD-10 CM/PCS system that will be implemented in the U.S. is significant in the degree of granularity and specificity found in the revised codes. This level of detail has also increased the number of codes exponentially. Excluding the procedure classification system (ICD-10 PCS) the diagnostic system of codes (ICD-10 CM) will increase from 13,000 in the current ICD-9 to upwards of 85,000 in ICD-10. The ICD-10 PCS currently includes 72,000 potential procedure codes. The data resulting from the conversion will be more comprehensive and greater in scope than the ICD-9 version. ICD-10 PCS was developed for exclusive use in the United States and is limited to classification of procedures and is descriptive in the context of anatomy, root operation or intent of procedure, approach employed, devices used and detailed qualifiers specific to the individual procedure. Both systems will be used to code diagnosis (es) and procedures assigned and documented relative to the individual patient.

Of importance to Risk Management is that the additional detail will provide a new depth and scope of information by which to forecast risk, manage health of populations and deliver care in increasingly safe environments. Demands for greater transparency of information will lead to enhanced accountability as decision-making processes will be described with greater clarity and consistency. The greater depth of information has both advantages and potential risks depending upon the accuracy and manner in which it is applied.

Not Just a Coding Issue:

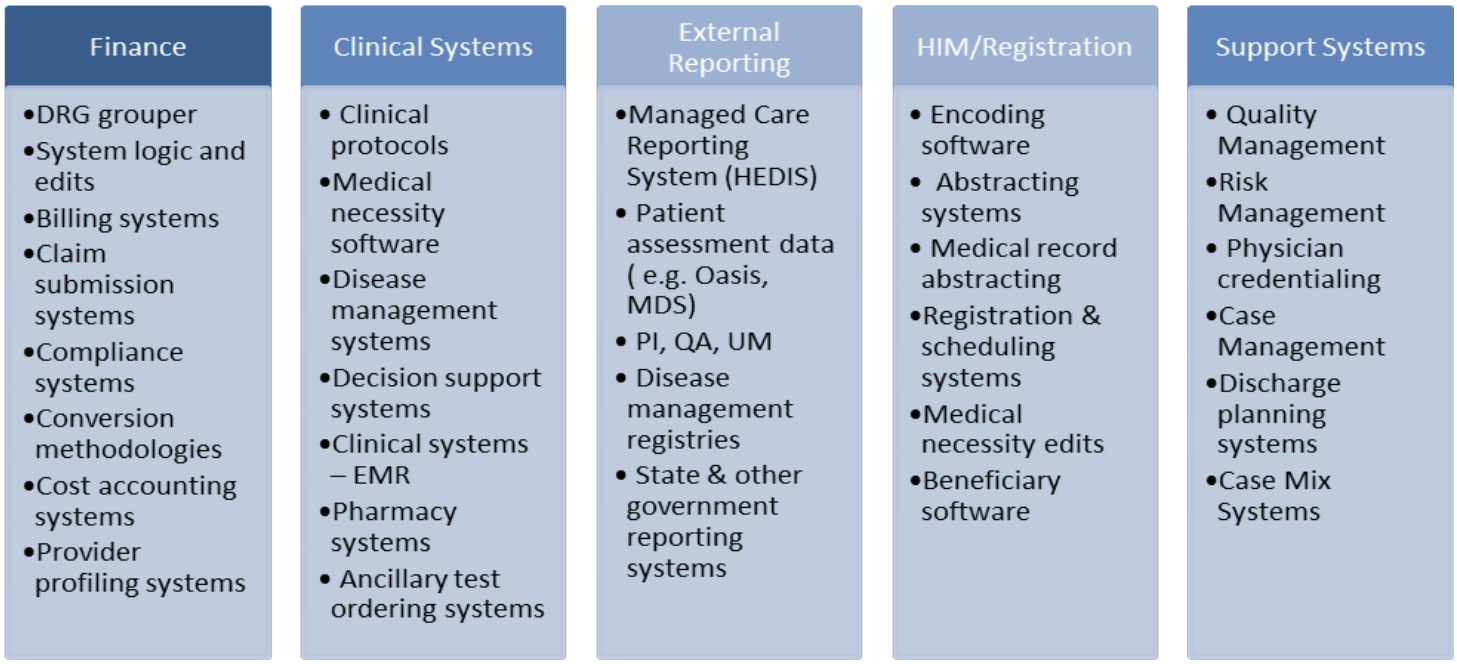
The ICD-10 conversion will affect all patient clinical data in every setting where information is accessed and applied to reporting and decision-making. (See figure 1.0). The paradox for risk management departments is that ICD-10 will not only provide better information for trending of risk factors and increased detail for event analysis but will also pose new challenges and risk points. Issues for consideration include:

- Information management mechanisms available for review of cases under litigation or scrutiny by external regulatory agencies. Some of these cases may fall under both ICD-9 and ICD-10 documentation requirements e.g. long stay patients overlapping the conversion dates, multiple incidents (falls), etc. Risk professionals will need an understanding of the new documentation requirements, how it impacts clinical management, the IT infrastructure supporting the documentation and the capabilities and willingness of the providers to comply with new standards for documentation.

- Audit activity which will now incorporate review of ambulatory and inpatient management simultaneously and across the continuum of care. The same tool that provides additional detail for risk assessments will be used to assist external regulatory agencies in the identification variation in clinical and billing practices. For example, OIG audits will be able to track variation and other inconsistencies across points of care.
- Medical documentation, which has always been important to support level of care, reflect standards of practice and provide evidence of medical necessity, will be precisely and directly linked to outcomes of care as well as bills submitted.

Gaps in detail or specificity always had the potential to reflect negatively in litigation or defense scenarios. Now that detail is prescribed and required to bill at specific levels of care both inpatient and ambulatory. For example, negative outcomes related to a procedure have specific codes and detail to describe the correlation between the outcome and the procedure or action. The physician will be required under the new guidelines and regulations to identify that correlation in the clinical documentation.

Figure 1.0 ICD-10 Impact Areas



Risk Management Strategies during Implementation:

Transparency and complexity are two cornerstones of ICD-10. The conversion process from ICD-9 to the ICD-10 system will pose risk in the areas of productivity, revenue stream and compliance. Productivity and revenue stream maintenance are receiving the greatest attention as finance and HIM departments prepare for go-live October 1, 2014. Of importance to risk management departments is the management of regulatory risks as the organization shifts from one language to the other. This "shift" goes beyond the usual change plan for adoption of new processes. This conversion goes much deeper to the core elements of clinical documentation (comprehensive assessment, communication, planning) that reflect the thoughtful process of clinical decision-making, risk identification and accountability for outcomes. As put by one federal monitor "we need to know the thought process that supports each clinical action and its relationship to the bill".

The HIMSS G7 Advisory Report (2011) identified five key areas of risk to the enterprise during the implementation and conversion phase. Although not an exhaustive list, these are high priority in that if not addressed these issues could have catastrophic consequences. CMS has been transparent and openly communicated in some venues that for those providers who have not prepared and do not have the required infrastructure the expectation is failure that may result in closure of facilities. The five key areas of risk include:

1. Financial impacts and sustainability
2. Work force management
3. Vendor and infrastructure readiness
4. Provider payment (hospital and physician)
5. Fraud, waste and abuse (HIMSS, 2011, p.3)

Strategies for managing risk during implementation begin with members of the risk department inclusion in planning and monitoring during implementation. Considerations during planning the planning phase minimally include:

- Availability of checks & balances to validate clinical documentation, claims remittance data and appropriate payment – internal self-auditing functions.

- New requirements for documentation and coding can be only be achieved through extensive education and training. Failure to adequately train personnel will affect coding and billing compliance under the new guidelines and audit processes. Few organizations have budgeted adequately for training. Physicians and any other professional responsible for clinical documentation and/or code assignment will need to be trained in the new system.
- Potential need to manage litigation cases during 18 month transition period using two documentation and coding systems due to the inability to map accurately from ICD-9 to ICD-10. Automated general equivalent mappings (GEMS) are in evolution and continue to require manual validation due to high error rate.

Risk management professionals bring unique and specific skill sets to the interdisciplinary team charged with managing the ICD-10 transition and conversion. The discipline is positioned to be excellent co-team leaders for the ICD-10 implementation task force given their knowledge of prevention, tracking and documentation of risk factors. In any case a representative from Risk Management should be an active participant on the implementation task force with the charge to ensure that appropriate "readiness reviews" incorporate risk issues and that processes of implementation include ongoing "checks and balances" of accuracy and compliance. Action items for the ICD-10 task force should minimally include:

- Review of current business priorities & strategic plan for impact areas e.g. new product lines or services where projected ROI will be directly impacted by changes in reimbursement. (It should be noted that reimbursement may improve or diminish depending on historical billing practices and documentation standards).
- Review and understand workflow and potential productivity impact in all areas. If root cause analysis requires analysis under ICD-9 standards *and* ICD-10 standards it will increase the time required to complete research and analysis.
- Validate vendors ICD-10 readiness.
- Project budget impacts in all areas for training, software upgrades and labor cost associated with diminished productivity during the 18-month transition period.
- Communicate and inform governance of scope and strategies for managing risk areas.
- Consider conducting gap analysis to determine if IT infrastructure and strategic plan adequately supports conversion issues.

Future Risk Management Applications & Opportunities Impacted by ICD-10:

Forecasting and managing risk within populations has been a primary goal since the inception of the classification system by the World Health Organization. Imbedded in the Accountable Care Act (ACA) are goals specific to managing and improving the health of populations. Risk management professionals have a history of patient advocacy as the identification of risk, monitoring of practice variation and promotion of standards improved care and served to protect patients. ICD-10 will provide data and substance to risk analysis that has been previously difficult. The role of Risk Management will continue to expand as organizations adopt new reimbursement and care management methodologies that assume risk such as bundled billing, management of Accountable Care Organization (ACO) infrastructure and Medical Home models.

Patient safety will continue as the primary initiative to support quality, manage cost and avoid the negative consequences of error. The ICD-10 system will provide data that links clinical history (risk), actions, location of event and other contributing factors to negative outcomes. An example of how the new system will provide more robust information is in the context of falls. The code(s) applied will identify underlying disease, history of falls, mechanism of fall, consequence or outcome of fall as well as the actions taken to manage the consequence (detailed information on procedural interventions). The role of Risk Management professionals will be essential in determining risk and implementing proactive risk management models.

Regulatory compliance will be a source of challenge as audit activity increases around processes and outcomes of care as well as the medical necessity of the care provided. Risk management professionals will need new competencies to lead the interdisciplinary team in building the processes and checks and balances required to protect compliance.

Physician integration and engagement will be dependent upon effective risk management systems and counsel as providers and entities partner to manage infrastructure and compliance requirements. Physician providers are struggling with impending changes that will change their work flow and approach to documentation significantly. Building on historical skill sets this will increasingly be an area where a strong risk management team, knowledgeable in the nuances of ICD-10, will collaborate with CDI specialists and others to facilitate and protect medical practice. For the organization RM functions are not just added value but a necessity for a successful transition.

In the words of William Bridges, "Change is not the same as transition. Change is situational the new site, the new structure, the new team, the new role, the new procedure. Transition is the psychological process people go through to come to terms with the new situation." Transitions change the world as we perceive it and are times of great risk and opportunity for those willing to meet the challenge.

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About the author



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AHIMA Approved ICD10 Ambassador Trainer

Professional Biography

Sandra Phillips Sperry is Principal & CEO of SPS and Associates. Her practice and professional experience encompasses hospital operations, executive coaching and business development. She is a transition management specialist who works with individuals and organizations to manage rapid cycle change.



Risky Business

"When Common Sense is Uncommon"

By: Pamela Monastero, MBA

COMMON SENSE TIPS FOR STAFF:

This quarter's column focuses on diagnostic errors in medicine. Countless articles have been written over the years on the topic of diagnostic errors in medicine—some of the older, comprehensive studies remain relevant today despite the passage of time. Various and diverse sources have conducted scientific case studies and physician surveys in attempts to de-mystify diagnostic errors. Despite the overwhelming literature, the detection and dissection of diagnostic errors continues to be a challenge for several reasons, some of which are: (a) provider failure to report diagnostic errors; (b) failure to detect errors that do not result in patient harm; (c) provider failure to recognize the diagnostic errors; and (d) continuity of care—patients leave a provider's practice and seek care elsewhere. Varied rationales have been put forth as to why diagnostic errors occur, including physician overconfidence in diagnostic abilities, diagnostic decision making (heuristics, intuitive, biases in decision making), communication among providers as well as systems-related factors such as specimen labeling, critical results reporting, abnormal test results and poorly managed transitions in care.[1] Clearly, discrete events (e.g. a wrong-sided surgery) are more readily captured and identified than events that occur over time (a delayed or missed diagnosis due to a failure to order appropriate testing or a failure of coordination among providers). Therefore, diagnostic errors sometimes 'fly under the radar' and thus present a challenge to risk management, quality assurance and patient safety processes because they are not generally part of existing surveillance or data collection.

In 2005, Graber wrote that "diagnostic errors receive little attention—a major factor in perpetuating unacceptable rates of diagnostic errors. Diagnostic errors are fundamentally obscure, health care organizations have not viewed them as a system problem, and physicians responsible for making medical decisions seldom perceive their own error rates as problematic. The safety of modern health care can be improved if these three issues are understood and addressed."[2]

Diagnostic Errors Defined

In terms of definition, a study reported in 2009[3] quantified diagnostic error as "any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis or a delayed diagnosis…including failure in timely access to care, elicitation or interpretation of symptoms, signs or laboratory results; formulation and weighing of differential diagnosis; and timely follow-up and specialty referral or evaluation." Studies of diagnostic errors reported in clinical journals are frightening: "as many as 40,500 adult patients in an ICU in the United States may die with an ICU misdiagnosis(es) annually[4]; diagnostic error underlies about 10% of adverse events occurring in hospital practice[5]; the causes of suboptimal cognitive acts were mostly mistakes (i.e. the planned action was incorrect), and this occurred in 163 of 247 cases reviewed (or 66%) and in 13.8% of those (34 cases) a diagnostic error occcurred[6,"] etc.

The 2009[3] study reviewed 583 physician-reported events and rated them as follows: 162 (28%) errors as major, 241 (41%) errors as moderate and 180 (31%) errors as minor. The most common among the missed or delayed diagnoses were pulmonary embolism (26 cases or 4.5% of the total), drug reactions or overdose (26 cases or 4.5%), various cancers—lung, colorectal, breast (60 cases or 10.3%), acute coronary syndrome (18 cases or 3.1%) and stroke (15 cases or 2.6%). The categorization of these diagnostic errors is as follows: 44% in the 'testing' phase (failure to order, report, follow-up on results), 32% in clinical assessment errors (failure to consider and overweigh competing diagnosis), 10% in history taking, 10% in physical examination and 3% in failure to refer, consultation errors and delays. The authors note that the most frequently delayed or missed diagnoses in this study mirrored those reported from prior studies of medical malpractice claims databases.

Analysis of Diagnostic Errors

"Errors of diagnosis are multifactorial involving both system-related and cognitive factors."[7] In 2009, the IHI identified the following contributing factors to diagnostic error: over-confidence, arrogance, inadequate information/feedback, incomplete follow-up, time pressures, failure to consult/share uncertainties, defensiveness and medical malpractice fears.[8]

In a study reported in 2005,[1,7] 100 cases of diagnostic error (from June 2004-November 2009) were identified via autopsy discrepancies, quality assurance reviews and self-reporting. 90 cases involved injury, including 3 deaths. 3 categories were used to categorize the errors: no fault (masked or unusual presentation of disease, patient was uncooperative or provided deceptive information), system-related (technical failure, equipment problems, organizational flaws) and cognitive (faulty knowledge/data gathering/synthesis). 7 cases were attributed to no fault and, of the remaining 93, the authors identified 548 different system-related or cognitive factors (5.9 per case). System-related factors contributed to the diagnostic error in 65%

of the cases and cognitive factors in 74%. In terms of system-related factors, the most common problems cited involved policies/procedures, inefficient processes, teamwork and communication. The most common cognitive problems involved faulty synthesis, with the single most common cause being premature closure—the failure to continue considering reasonable alternatives after an initial diagnosis as reached. Other common causes attributed to cognitive errors included faulty context generation, misjudging the salience of findings, faulty perception and errors arising from the use of heuristics.

The analysis of **system-related contributions** to diagnostic error identified the following:

- 13 encounters were technical or equipment related (instruments were faulty, mis-calibrated, unavailable);
- 35 encounters involved clustering (repeating instances of the same error type, e.g. incorrect reading of x-rays in the ED by covering physicians);
- 33 encounters were policy/procedure related (absent or incomplete policies that actively created error prone situations, e.g. no policy to ensure follow-up of patients after colon cancer surgery);
- 32 encounters of inefficient processes (lack of expedited pathways, delays in scheduling of patients for visits, testing, procedures, etc.);
- 27 encounters involving communication and teamwork;
- 23 encounters of patient neglect/failure to provide necessary care (cancer results not reported to patient);

The remaining encounters were categorized as management issues/oversight of systems (20--e.g. lost radiologic studies), coordination of care (18—e.g. multiple clinics/sites, hand-offs, consults), supervision (8—oversight of residents/PAs, etc.), expertise unavailable (8—specialists on call), training/orientation (7—clinician not made aware of correct processes, policies, procedures, e.g. special testing for diagnoses, etc.), personnel (4—staff laziness, attitude, etc.).

The analysis of **cognitive-related contributions** to diagnostic error identified the following:

- 11 encounters of faulty knowledge (4-insufficient knowledge of relevant condition; 7—insufficient diagnostic skill for relevant condition);
- 45 encounters of faulty data gathering (24—ineffective/incomplete/faulty work-up; 10—ineffective/incomplete/faulty history and physical examination; 7--faulty test/procedure techniques; 3—failure to perform screening procedures; 1—failure to collect required information from patient);
- 159 encounters of faulty synthesis related to information processing (e.g. failure to consider aspects of patients situation that are relevant to diagnosis, overestimating/underestimating usefulness or salience of a finding, missing signs/symptoms that are noticeable, delay to act timely, inappropriate conclusion based on reasonable data, etc.);
- 106 encounters of faulty synthesis related to faulty verification (e.g. premature closure and failure to consider additional possibilities, failure to order or follow up on appropriate test, failure to consult with an expert, failure to check previous clinician's diagnosis vs. current diagnosis, etc.).

The authors[7] concluded that cognitive and system-related factors often co-occur and that these factors may have led, directly or indirectly, to each other e.g. an inadequate history and physical examination can lead to a failure in ordering or interpreting appropriate tests or considering relevant diagnoses and referrals to specialists. An examination of the most common clusters/pairings were: (1) incomplete/faulty history and physical examination led to failure to consider the correct diagnosis and led to premature closure; (2) incomplete/excessive data gathering contributed to a bias toward a single explanation and led to premature closure; and (3) underestimating the usefulness of a finding led to premature closure and failure to consult.

Three conclusions were put forth by the authors[7]: (1) diagnostic error is typically multifactorial in origin; (2) system flaws contribute commonly to diagnostic error; and (3) cognitive errors are a common cause of diagnostic error and predominantly reflect problems with synthesis of the available information.

Reflections on Diagnostic Errors

Addressing the reduction of system-related contributors to diagnostic error is more readily accomplished when compared to developing strategies to address cognitive errors. Some suggested strategies to help address cognitive errors are simulation training, compiling comprehensive differential diagnoses (to avoid premature closure), apply the crystal ball experience (assume the working diagnosis is incorrect and develop alternatives to consider) and use of expert systems (computer-based clinical support systems, etc.). [7]

In the 2009[3] study cited previously, the two leading categories—testing and assessment--which accounted for 76% of the causes of the diagnostic errors—were determined to be "overlapping and inseparable" in nature. Because of this, the author's felt that an in-depth analysis of overlapping and clustering of certain patterns of errors would be useful to consider when designing error reduction and prevention strategies. The authors found the following:

- Introspection and reflection on cases involving diagnostic errors is a learning experience that can be shared with other providers creating more systematic approaches, checklists or automated decision support to aid in recalling, learning from and sharing such cases has the potential to help others to avoid repeating similar errors;
- Aggregating cases by diagnosis or diagnostic category allowed the authors discern patterns of failures that were not otherwise apparent. Inadequate follow up on abnormal images and erroneous attribution of a symptom to another diagnosis were frequent process errors;
- Additional study and analysis needs to be performed on diagnosis-specific vs. more generic types of improvement efforts;
- Diagnostic errors are categorized as cognitive vs. systems errors but the authors feel that the cases analyzed in the study demonstrates that there is overlap between the two;
- The decline in autopsies performed means that we could be burying our own mistakes as a rich source of information is no longer readily available.[2]

Strategies to Address Diagnostic Errors

What value can risk/quality/safety staff add to the identification and reduction of the incidence of diagnostic error?

1. First and foremost, we can assist in identifying system-related factors that contribute to diagnostic errors. Some of these might be identified through traditional methods such as medical malpractice claims dissection and analysis (the most frequently delayed or missed diagnoses in one study of diagnostic errors mirrored those reported from prior malpractice claims[1]), root cause analyses, failure-modes-effects-analysis (or proactive risk assessments), Tracers,[9] and Gemba walks[10]. Information gleaned by these efforts is essential to analyzing diagnostic errors and identifying trends and patterns that can be used to develop proactive measures to reduce the occurrence of diagnostic errors. Educational approaches might include interactive presentations (role play, polling of audience, "what would you do" scenarios, etc.), structured curriculum (web based or conference-style) prepared by risk/quality/safety staff to educate professional staff—obviously this is more attractive if Continuing Medical Education (CME) or Continue Nursing Education (CNE) credits are offered.

2. The Pennsylvania Patient Safety Authority[1,11,12] also recommends additional strategies to help reduce diagnostic errors:
   - System-level strategies:
     - Create a mechanism to collect diagnostic error reports within the facility to aggregate data to track, trend, determine patterns, provide learning across cases and measure improvement (there is a sample tool called the DEER Taxonomy Chart Audit Tool[1]). Also refer to #4 below;
     - Continuously improve the culture of safety to encourage identification and analysis of diagnostic error (capture as part of quality assurance process, adverse events reviews, etc.);
     - Perform drill down analysis of events that result in misdiagnosis-related patient harm (Graber's analysis of diagnostic error tool[12]).

   - Cognitive error strategies:
     - Provide resources for clinical decision support systems to provide accurate estimates of disease probability, e.g. web-based applications that assist physicians in making data-driven decisions at the point-of-care. Also see #4 below;
     - Encourage the use of clinical guidelines and algorithms;
     - Consider the use of diagnostic checklists to prevent reliance on memory. These also can be organized around high-risk diagnoses. Also see #3 below.

   Additional strategies can be found in the Pennsylvania Patient Safety Authority literature and on the website.

3. The Physician Checklist for Diagnosis[12] is a helpful tool that can be printed and distributed to clinical staff both as a patient safety resource and as a measure to help reduce the incidence of medical malpractice. The tool reminds the provider of the following:
   - Obtain your own, complete medical history;
   - Perform a focused and purposeful physical examination;
   - Generate an initial hypothesis and differentiate with appropriate additional questions, physical examination or diagnostic test;
   - Pause to reflect; take a diagnostic time-out
     - Was I comprehensive?
     - Did I settle on a diagnosis prematurely?
     - Have I made a diagnosis despite evidence to the contrary?
     - Was my judgment affected by any other bias?
     - Do I need to make the diagnosis now or can I wait?
     - What is the worst case scenario?
     - What are the 'do not miss' diagnoses that could be relevant?
   - Embark on a plan but acknowledge uncertainty and ensure a pathway for follow-up, including communication and transfer of information to the next provider of care.

4. Technology also offers innovative tools that can be utilized to identify potential cases of diagnostic errors. In a limited study as reported by Schiff13 in 2014 (300,000 patients over a 12 month period), technology was used to identify "red flags for prostate or colon cancer, elevated prostate specific antigen (PSA), positive fecal occult blood test (FOBT), rectal bleeding (hematochezia) and iron deficiency anemia. A refined electronic algorithm was then used to narrow the list to eliminate patients who were already known to have prostate or colon cancer and who had evidence of appropriate follow-up testing or referral." The list was then reduced to 1,500 possible patients who may have had a delayed or missed diagnosis. A manual chart review then ensued, with the conclusion that there were missed opportunities that represented an estimated 50 actual cancers per year. While helpful as a retrospective focused study, this information has limited use in "minimizing diagnostic errors prospectively." The author maintains hope that more can be done in terms of determining diagnostic screens/triggers and when these should be generated. Schiff created a table that outlines "where we are" (traditional ways of thinking about diagnosis and diagnostic error) and "where we need to be" (new paradigms/better ways to think about diagnosis and diagnosis improvement) which is helpful in quantifying thought processes surrounding diagnostic errors. Some suggestions include: setting up processes to reduce reliance on human memory inclusive of closer collaboration with staff (nurses, social workers, specialists the patient/family), "acknowledgement of ubiquitous cognitive biases" and making efforts to proactively address these, built-in alerts in workflows and standardization of processes, etc.[13] Clinical decision support technology (CDS) currently used includes programs such as DXplain[14] and Isabel[15] show promise as tools to assist physicians in constructing complete differential diagnoses.[16] Adoption of CDS technology is explored extensively in academic literature (refer to Recommended References for additional reading suggestions).

5. Other recommendations include developing programs for medical students and residents that focus on the science of cognition and decision making. In this era of speed and digital information, medical students and residents have readily available resources that may affect learning—a move away from memorization of "long lists of differential diagnoses"[16] and a possible dilution of the traditional model where skills are passed down from attending to resident.

Diagnostic Errors and Sentinel Events

When comparing diagnostic errors with sentinel event data reported to the Joint Commission,[9] we recognize that most data reported to The Joint Commission represents discrete events (such as wrong sided/wrong procedure/wrong patient-related events, retained foreign objects, medication errors, falls with injury, perinatal death/injury, etc.) which are more readily quantified than diagnostic errors. According to The Joint Commission, the most frequently cited root causes identified with reported sentinel events are human factors (e.g. fatigue, distraction), communication (among staff, across disciplines, with patients), leadership (e.g. lack of performance improvement structure, accountability) and assessment (patient observation processes, documentation). Of these factors cited, several can be directly applied to diagnostic errors made by providers, e.g. fatigue, distraction, communication (with other providers, office and hospital staff and with patients), assessment (documentation issues whether it is failure to document, incomplete or incomprehensive documentation re history/physical examination, etc. can contribute to the incidence of incomplete or incorrect diagnosis and poor follow-up with consultants and patients). Therefore, when diagnostic errors are recognized and reported, regardless of the incidence of patient harm, an in-depth analysis could be beneficial in identifying underlying contributing factors and developing corrective actions.

"The great majority of medical diagnoses are made using automatic, efficient cognitive processes, and these diagnoses are correct most of the time…there are exceptions: the times when these cognitive processes fail and the final diagnosis is missed or wrong. We argue that physicians in general underappreciate the likelihood that their diagnoses are wrong and that this tendency to overconfidence is related to both intrinsic and systemically reinforced factors."[17] Finally, while there is little in our tool box to address provider 'over-confidence' or arrogance, risk/quality/safety staff and leadership can work together to reinforce a culture that is transparent, driven by safety and focused on the improvement of systems, information management, analysis of resources and continued education on lessons learned to help reduce the incidence of diagnostic error.

At the time of this writing, the National Patient Safety Foundation (NPSF), as well as various other patient safety-related entities, posted a myriad of academic literature during Patient Safety Awareness Week (March 2-8, 2014). The NPSF site lists multiple resources, including guest speakers, and it is strongly recommended that clinical/risk/quality/safety leadership review the literature to better understand and, hopefully, implement measures to identify and prevent future diagnostic error.

References Listed on page 33

Dear Risk Manager:

This column, which will appear regularly in the AHRMNY Risk Management Quarterly Journal (RMQ), is designed to support both the novice and seasoned risk manager by presenting brief *pearls of wisdom* based on the experiences of our colleagues. This column is based on the contributions of our constituent members, to whom we are grateful for sharing their experiences. We continue to encourage our members to submit their experiences anonymously for inclusion in this column. Please e-mail any suggestions to pamela.monastero@nychhc.org or mail to AHRMNY utilizing the RISKY BUSINESS form which can be found on our website at http://ahrmny.com/images/downloads/Newsletters/form_risky_business_form_7_2009.pdf. The form permits confidentiality.

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TAKING YOUR RESTRAINT PROGRAM TO THE NEXT LEVEL:
STRATEGIES TO ADDRESS COMMON CAUSES OF PREVENTABLE PATIENT HARM AND DEATH ASSOCIATED WITH RESTRAIN USE



Caroline Brill, RN BSN JD CPHRM FASHRM
AVP, Healthcare Risk Management
AWAC Services

There may be times when a patient will require the use of restraints in order to prevent injury to himself/herself or others, or to prevent interference with his/her treatment. Generally, restraints include physical/mechanical devices used to reduce or restrict a patient's mobility. Other types of restraints may also include medications used to control the patient's behavior, and items designed to keep a patient in bed or prevent him/her from getting up. The Centers for Medicare and Medicaid Services (CMS), The Joint Commission and many states have developed regulations and standards for use of restraints and each carefully monitors adverse events that occur with restrained patients.[1]

A 2012 German study analyzed autopsy reports from the Institute of Forensic Medicine in Munich from 1997 to 2010. The results revealed 26 cases of death while the individual was physically restrained.[2]

The root causes included:

- Lack of continuous observation by clinical staff
- Restraints incorrectly fastened
- Use of non-standard restraints[3]

Similarly, here in the United States, within just over a six week period, six patients died in a Pennsylvania hospital following the use of chemical or physical restraints.[4] These figures are alarming and it can be surmised that a number of these deaths could have been prevented.

The implications associated with the use of restraints are apparent. However, it is often difficult for care providers to balance the need to use restraints in order to protect the patient or others from serious harm and keeping those very same measures from causing significant injury or death to the patient. In addition, clinicians must simultaneously consider and maintain practices that uphold patient's rights principles.

Risk mitigation strategies designed for the use of restraints in the health care setting begin with following the regulations and/or guidelines provided by legal, regulatory, and accreditation agencies. As previously mentioned, CMS, accreditation bodies, state laws and industry standards provide mandates and guidelines for the appropriate use of restraints designed to protect patient safety and patient rights.

However, merely adhering to guidelines and mandates has not proven effective enough to prevent serious injury and death associated with restraints. Despite the many regulations adopted, improper use of restraints and inadequate patient observation and monitoring have emerged as key areas to heed and address in order to elevate your restraint program to the next level.

Improper Use of Restraints

According to the federal rules, a patient may not be restrained for "coercion, discipline, convenience, or retaliation by staff."[5] At times, clinicians may be tempted to use chemical or physical restraints for their own convenience without consideration for other means to control a patient's behavior. Or, at other times, staff may restrain a patient to force him/her to take a medication or complete a procedure. In these latter situations, there can be a very fine line between the proper use of restraints and a violation of a patient's rights.

"Taking down" an aggressive patient is another situation presenting a "dangerous territory" from both the patient's rights and patient safety perspectives. From the patient safety aspect, many strategies used to effectively hold a patient down may restrict oxygen to the patient resulting in suffocation. To reduce patient harm in these situations, only designated staff members who are properly trained in nonviolent crisis intervention should be permitted to "take down" and physically restrain a patient ***after*** all reasonable alternative means (e.g., de-escalation techniques) have been exhausted or less restrictive means have been determined to be ineffective. Additionally, the use of restraints should be individualized, taking into account a patient's specific physical/psychological difficulties. From the patient's rights perspective, staff should be able to readily determine that the rationale for using such measures was to protect the patient or others from ***imminent*** and ***significant*** harm and not to punish a patient for displaying certain behavior.

Restraints and/or seclusion may be appropriate when, "… according to clinical judgment, less restrictive interventions are inadequate or inappropriate and the risks of these interventions outweigh the benefits."[6] The risk/benefit analysis involves focusing on the behavior at issue, considering all possible measures available, and analyzing each potential measure to determine which may be the least restrictive yet most effective to attain the goal. Documentation should properly reflect the clinician's risk/benefit analysis that supports that the proper restraint has been utilized and least restrictive measures were considered.

Sometimes the need to use restraints must be made in a split second in the interest of keeping the patient or others from immediate and significant harm, particularly in the emergency department or behavioral health unit. When faced with these split second decisions, an objective agitation assessment scale, such as the *Overt Aggression Scale*, may be utilized as a factor to determine whether restraints or seclusion may be immediately necessary.

Regardless of the clinical area where restraints may be utilized, formal processes that guide the risk/benefit analysis will facilitate proper restraint usage. According to the American Nurses Association (ANA), citing The Joint Commission, "Seclusion and/or restraint may be more likely to be employed inappropriately – that is, for non-emergency situations or circumstances where no significant risk of harm exists-when hospital unit staffing is inadequate or the staff is inappropriately trained to provide less restrictive interventions."[7]

An individualized approach should include a systematic assessment that includes an evaluation of the underlying causes of the patient's behavior. At that point, caregivers should incorporate the treatment designed to address the identified underlying causes of certain behavior, into the patient's plan of care. The ultimate goal is to eliminate the need for restraints.

Another way to reduce the use of restraints is to enhance annual staff education and training by facilitating brainstorming sessions to identify options for less restrictive interventions for different scenarios when a patient may require restraints. Begin by discussing various behaviors (e.g., pulling, scratching, frequent falls, agitation/ aggression, wandering) and identify several alternatives to restraints for each given behavior.

Inadequate Patient Observation and Monitoring

The Agency for Healthcare Research and Quality reported that hospitals with low nurse staffing levels tend to have higher rates of poor patient outcomes, including: pneumonia, shock, cardiac arrest, and urinary tract infections.[8] The report isn't shocking because common sense tells us that inappropriate nurse-patient ratios leads to poor care, including when restraints are used. Listed below are just a few examples of restraint deaths associated with inadequate staffing levels and lack of patient monitoring:

The root causes of a chemical restraint death in a Missouri hospital included failure to monitor the patient and inappropriate staffing levels.[9]

At a Pennsylvania hospital, a patient was found partially dangling from her bed while wearing a vest restraint. The patient's family successfully sued the hospital for wrongful death after the patient died from asphyxiation from a vest restraint. A review of the medical record revealed several late entries.[10] The multiple late entries may have suggested that the patient was not adequately monitored by staff.

In Georgia, a patient's body was found on the street below his hospital room window. The patient had been restrained by various methods during his hospitalization and was ordered to have a sitter at the time of the incident. A sitter was not available at the time of the incident.[11]

Facilities can avoid becoming the subject of similar headlines by ensuring that patient care units are adequately staffed and patients who are in restraints are properly monitored at appropriate intervals. To assist in improving patient safety when using restraints, facilities should enhance staffing models by ensuring that adequate patient acuity levels are assigned to patients who are in restraints and evaluate whether the proper use of unlicensed assistive personnel is maximized for each relevant clinical area.

Risk Management Tips[12]:

- Ensure that policies and procedures governing use of all restraints/seclusion comply with federal and state laws.
- Educate staff annually regarding assessment, de-escalation techniques, using least restrictive alternatives, and proper restraint application.
- Avoid restraining patients in the prone position in order to avoid asphyxiation.
- Thoroughly document all measures taken including, assessments conducted, least restrictive alternatives used, decision making process leading to restraint use and observations made during restraint use.

Conclusion:

Patients will at times require the use of restraints in order to prevent injury to themselves or to others, or to prevent interference with their treatment. A robust restraint program that addresses all aspects of restraint use, above and beyond minimum regulatory requirements, will promote safe and appropriate restraint usage practices while simultaneously preserving the patient's rights.

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About the author

Caroline Brill provides risk management education and consultation to Allied World's medical professional policyholders, helping them assess and manage their organizational risk. She works with policyholders to develop individual action plans to mitigate potential loss based on their unique exposures and risk management needs. Caroline also assists Allied World's health care clients with ongoing medical educational programs and policy and procedure review and development.

Caroline has over 20 years of healthcare experience. Her clinical expertise includes medical/surgical, critical care, and ambulatory care. She has extensive risk management experience in a variety of healthcare settings, including large hospital systems, critical access facilities, and physician office practices. Caroline earned a B.S.N. degree from Bowling Green State University and her J.D. from Cleveland Marshall College of Law. In addition to her designation as a Certified Professional in Healthcare Quality and Risk Management, Caroline is a member and Fellow of ASHRM. Caroline has served as a member of several ASHRM committees, including the patient safety insights committee, risk financing committee, and grants and scholarships committee. Caroline is a past board member of the Ohio Society of Healthcare Risk Management (OSHRM).

THE *ONE & ONLY* WAY TO PREVENT UNSAFE INJECTIONS IN HEALTHCARE

If spreading a dangerous illness at your facility or institution was entirely *preventable*, would you take steps to do so? As a risk manager, the answer surely must be a resounding "Yes!"

Yet, too few institutions are aware of the very real risks posed by unsafe injections in healthcare. In fact, the federal Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC)—a group of healthcare-related organizations dedicated to ensuring that safe injections happen in all healthcare settings—report that since 2001, more than 150,000 patients have been potentially exposed to bloodborne pathogens due to lapses in basic infection control procedures when preparing and administering injections.

These incidents include the notifications of thousands of patients that they might be at risk for potential exposure to hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), due to reuse of needles and syringes (including reuse of insulin pens and lancet devices from patient to patient), or misuse of single-dose or multi-dose vials. Patients have not only been exposed to viral infections due to unsafe injection practices, but also to serious bacterial infections, as outlined in this 2012 *Morbidity and Mortality Weekly Report* (MMWR) article: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm?s_cid=mm6127a1_w

All told, since 2001, 48 outbreaks of disease related to unsafe injections have been investigated by the CDC. However, risk managers might be interested to learn that this number only represents the incidents CDC *knows* about. The numbers cited could just be a fraction of the real cases, as many episodes of exposure risk are difficult to trace back to a healthcare setting.

So, unsafe injections are a very real and unfortunate reality in parts of the nation's healthcare system. Unfortunately some of the CDC investigations revealed that many providers who sincerely believed they were following correct injection procedures, were in fact making mistakes—potentially dangerous mistakes. For example, there is a mistaken belief on the part of some healthcare providers that merely changing a needle between patients makes a syringe safe for reuse. That is **not** the case!

In a handful of cases, the unsafe provider practices include reusing needles/syringes from patient to patient. But more commonly, these incidents include indirect disease transmission, where a healthcare provider inserts a used syringe (even if the needle has been changed) back into a multi-dose vial of medication, thus contaminating the entire vial of medicine if it is used for subsequent patients. Additionally, some providers mistakenly believe it is safe to reuse syringes if the injection is administered through an intervening length of intravenous (IV) tubing. In still other instances, a provider mishandles a single-dose vial, typically free of preservatives, in order to administer doses to multiple patients.

Correct procedures for safe injections are outlined in CDC's "2007 Guideline for Isolation Precautions: Preventing Transmission of infectious Agents in Healthcare Settings" (available at http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html).

Concern about these unsafe practices led to the creation of the *One & Only Campaign* ("One Needle, One Syringe, Only One Time"), http://www.oneandonlycampaign.org/, a public health education campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices. New York is a "partner state" in the *One & Only Campaign*, which is funded by the CDC and overseen by the New York State Department of Health (DOH). Healthcare providers and risk managers are urged to sign on to the *Campaign* and use the many educational materials including interactive infographics, videos, staff trainings, posters and brochures. Moreover, patients are encouraged to ask their providers questions, including "What steps are you taking to ensure my injection is a safe one?"

New *One & Only* materials, including an interactive infographic (suitable for accessing on a smartphone, tablet or personal computer) make an appeal to facility managers to "realize what's at stake" here. http://www.oneandonlycampaign.org/single-dose-multi-dose-vial-infographic

Likewise, the "Impacts of Unsafe Medical Injections" infographic outlines the potential for patient harm, loss of accreditation status for the healthcare facility and loss of license/livelihood to the provider. http://oneandonlycampaign.org/sites/default/files/upload/pdf/InjectionSafety-Infographic.pdf

The New York *One & Only Campaign* has also developed an archived injection safety "train-the-trainer" webcast with **free** CME/CNE/CHES credits, through the University at Albany School of Public Health/Empire State Public Health Training Center. This activity is suitable for training facility staff or in-services. http://www.albany.edu/sph/cphce/esphtc_injection_safety_webcast.shtml

Please take a moment to review all the educational materials including videos, posters, brochures, a podcast and the Bloodborne Pathogen Training Module at the *One & Only Campaign* website and start using them at your facility today! http://www.oneandonlycampaign.org

THE IMPACTS OF UNSAFE MEDICAL INJECTIONS IN THE U.S.

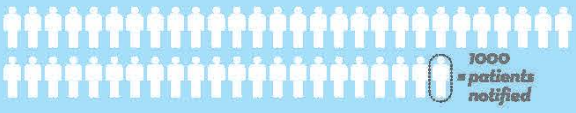
Unsafe Injection Practices Have Devastating Consequences

Syringe reuse and misuse of medication vials have resulted in dozens of outbreaks and **THE NEED TO ADVISE MORE THAN 150,000 PATIENTS...**

...to seek testing for bloodborne pathogens such as **HEPATITIS B, HEPATITIS C AND HIV** and have led to...

- Patient illness and death
- Legal charges/ malpractice suits
- Loss of clinician license
- Criminal charges

In just one clinic, syringe re-use to access medication vials for multiple patients resulted in an outbreak and one of the largest public health notifications in U.S. history.



50,000 PEOPLE EXPOSED TO INFECTION



$16-$20 MILLION IN COSTS

Outbreaks Occur in a Variety of Medical Settings



- Primary care clinics
- Pediatric offices
- Ambulatory surgical centers
- Pain remediation clinics
- Imaging facilities
- Oncology clinics
- Health fairs

Injection Safety is Every Provider's Responsibility

Steps Every Healthcare Provider Should Take



Needles and syringes should not be used for more than one patient or reused to draw up additional medication.



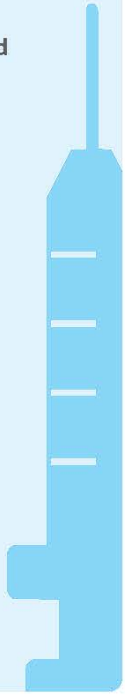
Do not administer medications from a single-dose vial or IV bag to multiple patients.



Limit the use of multi-dose vials, and dedicate them to a single patient whenever possible.



Speak up if you see a colleague not following safe injection practices.



ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

The ***One & Only Campaign*** aims to eradicate outbreaks from unsafe medical injections by raising awareness among patients and healthcare providers about proper practices. The campaign is a public health effort led by the Centers for Disease Control and Prevention (CDC) and produced by the Safe Injection Practices Coalition (SIPC), a collaboration of several medical societies, state health departments, patient advocates, and private medical companies.

FACEBOOK.COM/ONEANDONLYCAMPAIGN

@INJECTIONSAFETY

MANAGING EMPLOYED PHYSICIAN CLAIMS

By Jacqueline Bezaire, RN JD and Kenneth W. Felton, RN MS CPHRM DFASHM

This article addresses claim management for employed physicians by the hospital risk management or claim department through either a captive program or a self-insured retention.

Hypothetical

Competent Care Health System, an integrated delivery system, purchased a medical group and decided to roll the physician liability insurance into its captive insurance company. Doctor Jones just received a summons and complaint for a medical malpractice action alleging lack of informed consent, intentional battery and negligence. He put the summons aside because the medical group risk manager was no longer there and she was unsure how to report the claim to the hospital risk management staff. Months later, he saw the hospital risk manager in the hallway and told him about the claim. He assigned counsel from the captive panel; the attorney was able to have the default judgment set aside. The claim progressed slowly. Doctor Jones complained he was not kept informed on the progress of the case, did not agree with the choice of expert witnesses and that his best interests were not represented. The hospital/captive reserved its rights against the doctor for intentional acts and battery that were alleged in the compliant. He claimed that there was a conflict of interest and demanded separate counsel, which was hired at a cost of $300.00 per hour. An offer to settle came in from the plaintiff's attorney for $100. The doctor refused to settle unless he was dismissed from the case. The settlement was then made on behalf of the hospital; no report was made to the National Practitioner Data Bank (NPDB).

The New Partnership: Physicians and Risk Managers

As delivery systems shift from a volume-based fee-for-service model to a value-based care delivery system, primary and specialty physicians are seeking employment with various provider systems or networks in ever increasing numbers. Chances are good, therefore, that hospital risk managers will be involved in some aspect of managing physician claims. Whether the employer is a hospital, a hospital system, ACO or other entity, the relationship between physician and the risk management department is crucial in obtaining the best claim resolutions. In short, the better the relationship–the better the outcome.

Recent statistics show that physician employment could hit 75%, eclipsing private practice, in 2014. According to Merritt Hawkins, a physician recruitment firm, hospitals will employ three-quarters of physicians by 2014.[1] The reason for this migration to an employed rather than independent status is multifaceted and includes improved quality of life with schedules and time off, less administrative management responsibility, decreased medical malpractice insurance costs and improved benefits.[2]

As risk manager of an entity that employs physicians, your risk and claim management strategies are also changing. Physician claims are personal, because a physician's reputation or license may be at stake. Doctors are accustomed to physician insurance carriers fully managing these claims and providing risk management education. A physician carrier's management of a claim may be quite different from that of the entity's risk manager. Physicians are not always convinced that the hospital or other entity has their best interests in mind when resolving claims. They are also used to having a degree of control throughout the life of the claim. Trust must be established between the physician and the hospital risk management staff in order for claim management to be optimal.

SOME OF THE ISSUES

Claim Management and Claim Reporting

Physicians rolling into the hospital's program as employed physicians come from many different orientations on claim and incident reporting. Claim management will now likely be done under the direction of the hospital's risk management department. Confusion can develop on how the incident and claim reporting process should work. Incidents and claim reporting will likely take a new track and the risk of non-reported claims can increase. A clear and concise incident and claim reporting policy consistent throughout the organization must be developed. Training and dissemination of incident reporting forms should be done early in the physician's employment, preferably during orientation. Risk managers should strive for a policy that allows them to receive incident, claim and lawsuit information within 24 hours of an occurrence.

Determining Coverage

The claim handler for physician claims must determine whether or not the physician has coverage, whether the dates of the claim and notice provisions are met, and whether the employed physician is practicing within the scope of his/her employment.

The entity is responsible for the acts of the employee practicing within the scope of their employment. Sometimes the scope of employment is not clearly defined by the employment agreement and issues such as moonlighting and board involvement for other entities are not addressed. It is important to determine that the act giving rise to the claim occurred within the scope of the physician's employment or there may be no coverage for the physician. This issue should be addressed in employment contracts and insurance policy language.

Although, there is more flexibility with a captive insurance program to provide coverage, in some situations some entities may choose not to cover a claim of this nature. This determination should be made as early as possible in the life of a claim.

The general rules on whether an employer will be held responsible for the acts of the employee are:

- An employer is ALWAYS DIRECTLY LIABLE for its own negligence in hiring, training or supervising employees.
- An employer is ALWAYS VICARIOUSLY LIABLE for the wrongful acts of an employee within the scope of his or her employment.
- An employer MAY BE VICARIOUSLY LIABLE for the wrongful acts of an employee outside the scope of his or her employment.[3]

Any decision made as to whether an act or omission is within the scope of employment can be seen as a pattern of action for future claims that give rise to this same issue and should, therefore, be treated consistently.

Further complicating the issue of who is vicariously responsible for the acts of the employee are the many points of potential liability due to the various health care delivery models. Health care reform and the development of ACOs and other care entities might blur the picture. Any potential codefendants in the claim must be identified. The degree of participation or potential liability on the part of the codefendant will determine whether the entire matter should be tendered to the codefendant or apportioned between them.

Choice of Defense Counsel

Physicians may ask to select their own defense counsel. However, even most physician carriers have a panel of law firms from which to select. It is easiest to address this issue up front at the time of employment so that all parties agree on how to proceed when a claim comes in. Most organizations retain the right to select counsel from their panel and involve the physician in selecting from that defined panel.

Reservation of Rights

Typically, captive insurance companies do not reserve their rights in a medical malpractice matter. However, situations may occur where the entity's policy specifically excludes an act or omission by the doctor, such as allegations of fraud or criminal acts, which could cause the entity to issue a reservation of rights letter to the physician, advising that full coverage is not available for a particular claim. Although this sounds like a good idea on the surface, there are a few things to consider. First, it will likely alienate the physician who may not be particularly cooperative as the claim moves forward; it may deter other physicians from becoming employees; or it could give rise to an actual conflict of interest and a right to independent counsel in some jurisdictions. Although most captives rarely reserve their rights, the manner in which these potential conflicts are managed is important; managing expectations early is key to an optimum outcome on the claim.[4]

Conflict of Interest and Right to Independent Counsel

The entity that holds the captive insurance policy is now the insurance company in most respects and must afford such rights as due to the insured physician under state laws. One of these laws might be the right to separate counsel when there is a conflict between the insurance company and the doctor. These conflicts can occur when all of the acts or omissions alleged in the complaint are not covered and a reservation of rights has been made as described above. If all allegations are not covered under the captive policy, the defense of the employed physician might conflict with the interests of the captive/entity. In some jurisdictions, this may trigger the right to independent counsel for which the insurance company (captive) will have to pay reasonable attorney fees.[5]

When other hospital employees are involved, physicians may deem it necessary to implicate them in defense of their claims. Because both the physician and the other implicated employees are employed by the same entity, the defense of the matter would probably not give rise to a conflict of interest, as the defense is aligned. However, it has been argued that if there is a reporting requirement to the NPDB, the defense may not be aligned and a conflict exists.[6]

Consent to Settle or Try A Claim

Who makes the decision to try or defend the case, or, if it is to be settled, for how much? Physicians have a personal interest in the outcome of their claims not only for reputation's sake but also for reporting to state and national medical practice data banks.[7]

The first thing to look at is the captive policy. Is there a settlement clause in the policy and does it clearly state who has the authority to settle a claim? This needs to be viewed in light of state statutes. With most captive policies, the consent to settle lies with the hospital; however, a few states take the position that the physician has the ultimate right of settlement and give the physician a statutory right to consent to settle a medical malpractice claim.

These states require that the physician give consent before the insurer can settle a professional liability claim on his or her behalf. The California Business and Professions Code, § 801.1(j), for example, states, "Notwithstanding any other provision of law, no insurer shall enter into a settlement without the written consent of the insured. ... The requirement of written consent shall only be waived by both the insured and the insurer."[8]

If the state has such a statute, the law must be followed regardless of what the captive policy says. If the captive policy is silent on the issue, the position taken must be consistent over time in similar circumstances.

Physicians are accustomed to consent to settle language from their medical malpractice policy. The issue becomes: Who has the right to consent or prevent settlement if the physician is an employee? Usually the entity would have the consent unless the policy or a contract specifies something different in an employment situation. Physicians are typically not pleased with no right to consent

to settlement because they feel that it is their reputation at stake and that they have limited or have lost control of the process. They are not always convinced that the entity has a doctor's best interests in mind when settling a case.

The best way to deal with consent issues is to address them before a claim occurs and delineate this in the captive insurance policy or the employment contract so that expectations of all parties are aligned from the start.

Assuming that the physician agrees to settle a particular claim, the amount of the proposed settlement becomes very important because it may trigger state and federal settlement reporting requirements.

Settle on Behalf of and the NPDB

A technique often used by defense counsel is to dismiss the doctor from the case and settle the claim on behalf of the hospital. Is this a good technique or are there ramifications to this approach?

A case settled on behalf of a physician must be reported to the NPDB. So removing the doctor from the action is seen as a way for the hospital to protect the doctor. Also known as "shielding," this technique has been known for years but has recently become more prevalent.

The data bank is a federally run register that is supposed to record all serious disciplinary actions taken against doctors and any payments made on behalf of doctors, because of either a verdict or a settlement, in a medical malpractice case.

The purpose of the data bank is to protect consumers by providing information to make decisions on whether to hire or discipline a doctor.[9]

If a practitioner is dismissed from a lawsuit prior to the settlement or judgment, any payment made to the plaintiff is not reportable. Also, payments made by the practitioner in a personal capacity are not reportable. However, if the dismissal from a lawsuit is a condition of a settlement or release, then the payment is reportable. Thus, it is important for physicians to monitor all malpractice litigation (even if payments are to be made by the hospital or insurance carrier) and to obtain early dismissal before settlement negotiations are undertaken.[10]

In addition, the regulation in the data bank's guidebook says in bold face that "if the practitioner is dismissed from the lawsuit in consideration of the payment being made in settlement of the lawsuit, the payment can only be construed as a payment for the benefit of the health care practitioner and must be reported to the NPDB."[11] However, patients' lawyers maintain that regulation still depends on the hospital, or the hospital's insurance carrier, admitting to the data bank that the doctors were removed as a condition of the settlement – which, they say, almost never happens.[12]

Although settling on behalf of the hospital or entity instead of the physician appears to defeat the purpose of the NPDB, whether or not to use this technique is a decision for the entity and its attorneys.

Playing Nice in the Sandbox—Risk Management Techniques

Physicians are used to having control over their medical malpractice claim process, so they will need to trust the claim management changes inherent in the employee arrangement. Techniques for fostering this trust are simple and go a long way to eliminating some of the issues above.

- Involve the physician employee, group or representative in the claim process as much as possible by allowing active participation in claim management policy and education.
- Develop a clear claim reporting process (i.e., a written policy for claim and incident reporting) and advise physicians on any changes from their prior process and experience.
- Establish a working relationship between the employed physicians and the risk manager. The risk manager should be visible and available to physicians providing education and process development in claim and risk management activities.
- Risk management should provide continued support and peer resources for strong provider reaction to malpractice claims.
- Consider developing a claim management committee where physicians are represented and involved in claim decisions.
- Determine where settlement authority lies. Often this is a matter of how much money is anticipated to settle the claim and settlement authority would be granted in a specific amount. Do this in advance of a claim, ideally at the time of employment.
- If there is a settlement, inform the physician what is being reported to the NPDB or state data banks.
- Manage expectations of choice of counsel in advance by developing a defense attorney panel with physicians.
- Keep the physician informed on the progress of the claim by copies of correspondence and input from expert witnesses.
- Involve physician in all aspects of settlement negotiations and seek his/her input.
- Address in advance the need for the physician to be available for trial and settlement negotiations.
- Thoroughly prepare the physician to understand the implications of body language, vocal tones and message when testifying if a trial seems inevitable.
- Review employment contracts for the presence of consent issues.
- Closed claim reviews should be mined for information for future risk management loss prevention educational offerings.

Conclusion

Handling medical malpractice claims for an employed physician requires attention to the unique interests and concerns of individual doctors as well as employing best practices in claim management. Communication and managing expectations at the start of a physician's employment are vital. Another key component in obtaining optimal claim outcomes is the involvement of employed physicians in all aspects of claim management

policy development that might affect them. When changing policies and loss prevention education, risk management should include physicians whenever possible. Physicians should be strongly encouraged to take an active leadership role in risk management issues.

The ancient adage "*united we stand and divided we fall*" aptly describes the relationship between an employed physician and a captive insurance company. The success of a captive claim management program depends on a committed, coordinated effort among all parties.

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NEW YORK HEALTHCARE LEGAL ROUNDUP: 2013 YEAR IN REVIEW

By Stacey P. Klein

The year 2013 brought a tidal wave of reforms affecting New York healthcare providers and was a robust year for bolstering the government's enforcement capabilities. Even setting aside the myriad issues health care providers faced in 2013 in the wake of the rollout of the Affordable Care Act, the breadth and scope of the changes affecting health care delivery have made it difficult for providers to keep pace. We summarize the top 10 statutory and regulatory enactments of 2013 impacting health care providers in New York.

1. Hitech Omnibus Regulations

Early last year, the U.S. Department of Health and Human Services (HHS) published the long-awaited final regulations modifying the HIPAA Privacy, Security, and Enforcement Rules as required by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). The HITECH Regulations strengthened the government's ability to enforce the HIPAA regulations by making business associates and their subcontractors who are given access to Protected Health information (PHI) and entities, including individuals that maintain and transmit PHI on behalf of a "covered entity" subject to regulatory obligations to comply with HIPAA. The final regulations make business associates directly liable for non-compliance with certain of the privacy and security regulations. The Final HITECH Regulations became effective on March 26, 2013, but HHS gave covered entities and business associates until September 23, 2013 to become fully compliant. Business associate agreements entered into, modified or renewed after January 25, 2013 must already comply with the new requirements for business associate agreements. All existing business associate agreements will need to be revised to comply with the new regulations by no later than September 23, 2014. Staff will also need to be appropriately trained to comply with the revised rules.

2. Physician Payments Sunshine Act

On February 8, 2013, CMS published the Final Regulations for the Physician Payments Sunshine Act (the Sunshine Act). The Sunshine Act requires manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) to disclose the types of direct and indirect payments and transfers of value they make to physicians and teaching hospitals. Manufacturers and group purchasing organizations (GPOs) must also report certain information regarding the ownership or investment interests held by physicians or their immediate family members in such entities. Even charitable donations on behalf of physicians or hospitals may require disclosure. Certain exclusions from the reporting requirements exist, including de minimis the provision of educational materials for the benefit of patients.

Manufacturers and GPOs were required to begin collecting the required information beginning on August 1, 2013 for an initial reporting period ending December 31, 2013. Initial reporting of such data to CMS was supposed to be made by March 31, 2014. However, in February 2014, CMS announced a delay, establishing a two-phased approach to the deadline for the first reporting year. During Phase 1, which runs until March 31, 2014, CMS requires individual user registration with its so-called Open Payments system, submission of corporate profile information and aggregate 2013 payment data via e-mail. Phase 2, which is set to begin in May and extend for no less than 30 days, will involve industry registration with the Open Payments system, submission of detailed 2013 payment data, and legal attestation to the accuracy of the data as required by the Final Rule. CMS maintains that it still is on track with its plans to publish the payment information reported to it on a website, currently under development, by September 30 2014. CMS also plans to make certain non-public information reported to it available to researchers.

Hospitals, physicians and other individuals and entities have the right to dispute and correct the information reported by manufacturers and GPOs prior to such information becoming public, but must do so in the manner and within the time frame specified by CMS. If a dispute cannot be timely resolved, CMS will publish the original and attested data, but will mark it as disputed. It is imperative that providers and other individuals and entities promptly review the proposed reports of payments and transfers of value to them to dispute and correct inaccurate and/or misleading information in the manner prescribed by CMS prior to publication on the CMS website. It is likely that the published information will be scrutinized for purposes of determining whether any violations of federal and applicable state laws, including, but not limited to, the Anti-Kickback Statutes, False Claims Acts, and Stark Laws, were committed.

3. Safe Act

The New York Secure Ammunition and Firearms Enforcement (SAFE) Act of 2013, a measure passed to curb gun violence, imposes certain reporting obligations on mental health professionals in New York, which are defined to include physicians, psychologists, registered nurses, and licensed clinical social workers. Mental health professionals must report to the Director of Community Services (who reports to the Division of Criminal Justice Services) if they are providing treatment to a person whom they believe, in the exercise of reasonable professional judgment, is likely to engage in conduct that would result in serious harm to self or others. The SAFE Act requires that such reports be made "as soon as practicable." Information submitted to the

Division of Criminal Justice Services, which is limited to names and other non-clinical identifying information, license should be suspended or revoked, and whether a person's guns should be removed.

The SAFE Act provides some protection for reporting mental health professionals. For example, a mental health professional is not required to act if, in the exercise of reasonable professional judgment, such action would endanger the mental health professional or increase the danger to a potential victim or victims. In addition, any good faith decision made by the mental health professional regarding whether to report to the Director of Community Services cannot be used as the basis for any civil or criminal liability of the mental health professional.

4. Sepsis

New York became the first state to require all hospitals to adopt best practices for the early identification and treatment of sepsis, a condition that was a leading cause of death in hospitals in 2013. The regulations include guidelines regarding current best practices for treatment of sepsis and require hospital protocols to clearly identify how treatment will differ for adults versus pediatric patients, but otherwise permit facilities to adopt protocols that work for them, subject to New York State Department of Health (DOH) approval. DOH has issued guidance documents that provide greater detail with respect to the required components of hospital protocols for severe sepsis and septic shock for adults and for children. Consistent with the regulation, all hospitals were required to submit protocols by September 3, 2013 and once approved, to implement such protocols by December 31, 2013.

Once adopted, hospitals must obtain DOH approval of their sepsis protocols once every two years, or sooner, as DOH may require, and provide the DOH with its risk adjusted mortality measures for sepsis annually, or more frequently at DOH's request. The protocols must be updated periodically and staff with patient care responsibilities must be trained to properly execute the procedures.

5. Pediatric Regulations

DOH proposed and finalized regulations that target pediatric hospital patients and their distinctive needs in 2013. The regulations require hospitals to have age appropriate equipment and supplies, proper age and size dosing of medications, and require personnel in the emergency department and pediatric intensive care unit have the skills to properly assess and manage critically ill or injured pediatric patients and resuscitate such patients. Hospital policies and procedures must be updated regarding standards for clinical appropriateness of imaging studies, including the appropriate radiation dose, image quality and patient shielding. and ensuring imaging study orders are specific to the body part(s) that are to be imaged. Hospitals are required to establish a separate pediatric unit if the hospital regularly has 16 or more pediatric patients or if pediatric patients cannot be adequately and safely cared for except in separately certified pediatric beds. A hospital that cannot meet all of the staffing, space and equipment requirements will have to develop criteria, as well as policies and procedures for the transfer of pediatric patients.

Pursuant to the new regulations, hospitals must allow at least one parent or guardian to remain with a pediatric patient at all times and post a "Parents' Bill of Rights" informing parents and guardians of the protection afforded by the regulations. The regulations require hospitals to develop and implement policies and procedures related to the review of critical value test results, ensure patients are not discharged while critical value tests are pending, ask for the name of each patient's primary care provider and forward laboratory results to the patient's named provider. Hospitals will also need to implement protocols specifying when supervising or attending physicians must be present.

The regulations added provisions regarding Pediatric Intensive Care Unit (PICU) services, including requirements that a PICU be approved by DOH and that a hospital's governing body develop written policies and procedures for operation of the PICU.

The regulations also include rules not specific to pediatrics, including reporting requirements regarding licensed and unlicensed health profession students who withdraw from instructional programs or are terminated due to mental or physical incompetency, disciplinary issues, and endangerment of patient safety.

Hospitals must comply with these regulations by March 31, 2014. To do so, hospitals need to update their policies and procedures and implement certain newly required policies and procedures. Hospitals may also need to hire additional staff, procure additional equipment and supplies, require additional staff certification and training, and set aside space for pediatric patients.

6. Electronic Prescribing And Dispensing

The past year has also seen a number of changes to the way prescriptions for controlled substances may be prescribed and dispensed. The DOH adopted regulations authorizing practitioners to issue electronic prescriptions for controlled substances in Schedules II through V, permitting pharmacists to accept, annotate, dispense and electronically archive such prescriptions, and requiring maintenance of records related to such prescribing and dispensing. The regulations require all practitioners and pharmacists engaging in electronic prescribing and dispensing of controlled substances to utilize computer applications that meet federal security requirements and that such computer applications be registered with the State Bureau of Narcotic Enforcement. The regulations provide that prescription information retained electronically should be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of data.

By March 27, 2015, all prescriptions, including prescriptions for non-controlled substances, issued in New York State must be electronically transmitted, with certain limited exceptions. DOH is permitted to issue waivers to practitioners

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that apply based on a showing of economic hardship, technological limitations and exceptional circumstances.

The regulations require proper safeguarding of practitioners' credentials issued for the purposes of signing electronic prescriptions and reporting if practitioners discover such credentials have been lost or compromised. The regulations also provide guidelines for the prescribing of controlled substances to a patient as part of a continuing therapy by a covering practitioner during the temporary absence of the initial prescriber.

Additional DOH regulations, effective August 27, 2013, require practitioners consult the Prescription Monitoring Program (PMP) Registry prior to prescribing controlled substances to patients, except under certain circumstances specifically enumerated in the regulations. Each New York State licensed prescriber and pharmacist must have an individual Health Commerce System (HCS) account to access to the PMP Registry. Practitioners and pharmacists are permitted to authorize a designee to consult the PMP Registry on their behalf. Unlicensed residents or interns of a medical teaching facility may access the PMP Registry on behalf of a hospital if registered as a PMP Designee on behalf of such hospital. However, a prescriber may not delegate the transmission of electronic prescriptions to an agent or employee.

The regulations also change the frequency by which dispensing practitioners and pharmacies must submit dispensed controlled substance data to DOH, and include a requirement for reporting that no controlled substances were dispensed.

Physicians, pharmacists and other health care providers must implement practices to ensure compliance with the rigorous new prescribing rules. Teaching hospitals will need to implement policies to ensure that medical students and any unlicensed residents have the appropriate access for prescription review.

7. Executive Compensation

The DOH, along with 12 other state agencies, including the Office of Mental Health and the Office of Alcoholism and Substance Abuse Services, adopted final regulations limiting executive compensation paid by, and administrative expenses paid to, "covered providers" receiving state funds or state authorized payments. The final regulations were designed to implement Governor Cuomo's Executive Order 38, issued in January 2012, to limit "excessive" compensation and administrative expenses of service providers that receive state funds or state-authorized payments of federal funds.

The regulations limit the use of state funds or state-authorized payments for executive compensation to $199,000 a year and limit the use of such funds to pay the covered provider's administrative expenses. "Covered providers" are providers that have received state funds (including Medicaid) or state-authorized payments that (1) have averaged over $500,000 a year during the covered reporting period and the prior year and (2) account for at least 30% of the provider's total annual in-state revenue during the same time period.

An executive's total annual compensation may exceed $199,000 by paying for the excess above $199,000 with non-state funds or state-authorized payments, but only if: (1) the provider obtains a waiver from DOH, or (2) the compensation (a) does not exceed the 75th percentile of compensation paid to executives in comparable positions and geographic areas, and (b) was reviewed and approved by the provider's board of directors or governing body (or a compensation committee thereof), with at least two independent directors, relying on comparability data. A covered provider is also prohibited from using more than 25% of state funds or state-authorized payments to pay for administrative costs. This limit decreases by 5% per year to 15% by 2015.

The final regulations became effective July 1, 2013, however the limits do not go into effect for covered providers until the first day of its covered reporting period. For providers who file cost reports, the date is January 1, 2014. For all other providers, the date is either the first day of the calendar year (i.e., January 1, 2014) or the first day of the provider's fiscal year beginning on or after July 1, 2013 (i.e., sometime between July 1, 2013 and June 30, 2014).

8. Smoking Prohibition

Effective as of October 29, 2013 smoking is prohibited outdoors on the grounds of general hospitals and residential health care facilities or outdoor areas within 15 feet of the entrances or exits to the buildings or grounds of such facilities. A narrow exception permits a residential health care facility to designate a separate outdoor area on the grounds where patients, visitors and guests may smoke, provided the area is not within 30 feet of any building structure. This exception does not apply to hospitals or employees of residential health care facilities. However, DOH clarified that the smoking ban does not apply to private automobiles and therefore employees may smoke in their own cars while parked on the grounds of the facility, unless the facility prohibits this through their own policies. Facilities must update their policies and inform their staff concerning these changes. Facilities are also required to post signs alerting the public that smoking is prohibited.

9. Non-Profit Revitalization Act Of 2013

The Non-Profit Revitalization Act of 2013, which was signed into law at the end of 2013, is being hailed as the first major reform to New York's charities laws, including the Not-for-Profit Corporation Law (NPCL), in over 40 years and will impact the governance of most New York non-profit corporations. The Act is intended to improve governance, increase accountability and modernize state laws in ways that will lessen regulatory and administrative burdens on not-for-profit corporations governed by the NPCL. Most of the Act's changes take effect on July 1, 2014. Some of the key governance changes include new requirements for audit oversight, tighter restrictions on related party transactions, new requirements for conflict of interest policies and whistleblower policies, and greater Attorney General enforcement authority, including

giving the Attorney General clear authority to bring judicial proceedings to unwind related party transactions. Important administrative changes that provide some relief to charities include permitting the use of electronic communications for certain meetings, lowering the board approval threshold requirement for routine real estate transactions, eliminating the letter types (A, B, C or D) in favor of "charitable" or "non-charitable" designations, and increasing the threshold for financial reporting. Accordingly, existing corporate documents including Corporate Bylaws, Conflict of Interest Policies, Whistleblower Policies; and Related Party Transaction Policies will likely require changes to conform to the new law.

10. Observation Status

Last year also brought a lot of changes to the rules regarding patient observation versus patient admission. A new state public health law adopted in 2013 requires general hospital providing observation services to develop and adopt policies and procedures for observation services, and provide such services in the proper clinical location and a distinct physical space, if appropriate. Following the new law's enactment, DOH issued programmatic guidance to hospitals, providing that observation services may be provided for up to 48 hours in a distinct unit and/or inpatient beds. DOH permits critical access hospitals and sole community hospitals to utilize emergency department beds for observation services. Hospitals with existing waivers and existing observation units in compliance with current regulations are permitted to continue to operate their observation units for now. The guidance also outlined the new New York State Medicaid reimbursement policy for observation services, which will reimburse for up to 48 hours of observation services under specific circumstances if a patient is placed in observation status for a minimum of eight hours with clinical justification.

Another New York State law, enacted in October 2013, which became effective January 19, 2014, called the Notice of Observation Services Act requires hospitals to provide both oral and written notice to patients within 24 hours of placing patients in observation status. The notice of must include a statement that the patient has not been admitted to the hospital and is receiving observation services, when the observation services began and that the patient's observation status may impact the patient's coverage for the hospital services, as well as coverage for any subsequent discharge to a skilled nursing facility, home, or community-based care. The notice must also advise the patient to contact his or her insurance plan to better understand the implications of being placed in observation status. The patient or the patient's legal representative must sign the notice to acknowledge receipt, and if a patient or the patient's legal representative refuses to sign, such refusal must be documented. DOH has issued a model notice form containing the required information.

Another new rule regarding patient observation status, known as the Two Midnight Rule, was published and went into effect in 2013 but CMS has delayed its enforcement until October 1, 2014. This date is but the latest in a series of extensions CMS has given regarding enforcement of this rule, which has become the subject of an industry-wide outcry and lawsuit.

The Two Midnight Rule provides that a Medicare patient's hospital admission would only qualify for Part A reimbursement if the physician admitting the patient expects that the treatment will require an inpatient stay lasting at least two midnights at the time of admission. Otherwise, the stay is required to be billed as outpatient services under Medicare Part B.

During the period in which enforcement is delayed, CMS stated that Medicare administrative contractors (MACs) and recovery audit contractors (RACs) will not conduct pre- or post-payment status reviews for compliance with the Two Midnight Rule. Rather, they will conduct "probe and educate" reviews for claims with dates of admission of March 1, 2014 to September 30, 2014 by reviewing a sample of claims for compliance and conducting educational outreach efforts and repeating the process if necessary. However, as CMS reviews claims to "probe and educate," compliance failures unrelated to the Two Midnight Rule may be subject to post-payment audit activities under other currently effective rules, such as the reasonable and necessary standard.

Bipartisan legislation introduced in the Senate on March 5, 2014, entitled the Two-Midnight Rule Coordination and Improvement Act of 2014, codifies the CMS delay in enforcement for claims made through September 30, 2014 and prevents CMS from making the probe and educate audits more onerous on hospitals than they are under current CMS guidance. The bill also requires CMS to adopt a payment methodology for short inpatient stays under Medicare and delays the enforcement of the Two Midnight Rule for claims on or after October 1, 2014 until the earlier of the implementation of the payment methodology for short inpatient stays and October 1, 2015. This bill has already garnered widespread support among hospitals and other providers.

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