



Kansas Department of Health and Environment
Bureau of Child Care and Health Facilities
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Annual Risk Management Report for 2009

“First, Do No Harm - Preventing the Avoidable”

Primum non nocere - First, do no harm - is commonly known as the Hippocratic Oath governing the actions of physicians, and healthcare providers in general. This oath does not ask for perfection, but that the individual will practice and prescribe to the best of their ability and judgment, for the good of the patient, and try to avoid harming them. The good of the patient is the highest priority.

Provision of the best care possible with the good of the patient as the highest priority is not only the right thing to do, but it is smart business. When the focus is on quality patient care that prevents avoidable adverse events, quality improves and risks are reduced. Satisfaction of the patient and the provider are increased. Everyone wins.

On 4/8/08, HealthGrades identified in their fifth annual Patient Safety in American Hospital Study that patient safety incidents, during the three year period of 2004 – 2006, resulted in 270,491 deaths with 238,337 of these identified as potentially preventable. These incidents cost Medicare \$8.8 billion. The analysis included 41 million Medicare patient records representing approximately 3 percent of all Medicare admissions. The analysis disclosed 1.1 million patient safety incidents. These findings identified that top-performing hospitals averaged 43 percent less chance of one or more medical errors compared to the poorest-performing hospitals. The report proposed that if all hospitals were top-performing, approximately 220,106 of the patient safety incidents and 37,214 of the deaths could have been avoided. The Medicare savings would have been \$2 billion. Dr Samantha Collier, HealthGrades’ chief medical officer and the primary author of the study stated, “While many US hospitals have taken extensive action to prevent medical error, the prevalence of likely preventable patient safety incidents is taking a costly toll on our health care systems – in both lives and dollars.”

After more than a year’s notice, Medicare stopped paying hospitals for avoidable errors - effective October 2008. These errors include infections, wrong site surgery, serious pressure ulcers (stage III or IV), etc. Other healthcare insurers also no longer pay for expenses related to medical errors.

Just as it is inappropriate for an auto mechanic who accidentally breaks your windshield while trying to repair the engine of your car to bill you to fix his mistake, hospitals and other healthcare providers should be held accountable for their errors.

An article entitled “Medicare this week stops paying for the cost of preventable hospital errors” was published on Everything Cleveland on September 29, 2008. Per this article, Medicare reported more than 250,000 people had serious pressure ulcers while hospitalized in 2007. Each case cost Medicare approximately \$43,000 in hospital expenses.

In March 2009, CDC (Centers for Disease Control and Prevention) released a report entitled, “The Direct Medical Costs of Healthcare-Associated Infections in US Hospitals and the Benefits of Prevention.” The report summarized that the overall annual direct medical costs of HAIs (Healthcare-Associated Infections) in US hospitals ranged from \$28.4 – 45 billion. The range of savings for effective utilization of infection control interventions were:

- 1) \$5.7 – 6.8 billion with 20 % infections preventable
- 2) \$25 – 31.5 billion with 70% infections preventable.

A July 9, 2009, article entitled “Pressure Ulcers and Wound Care” was released. This article was written by Richard Salcido MD, Professor of Rehabilitation, and Adrian Popescu MD, Research Fellow. Both are with the University of Pennsylvania School of Medicine. Dr Salcido reported that pressure ulcers have affected mankind for ages and has become a prominent national healthcare issue, but they continue to remain a major cause of morbidity and mortality. The cost of treatment was \$2000 - \$40,000 per pressure ulcer, depending on the stage of development.

In addition to these costs are tolls directly on the patient and their families. Although the juries have attempted, it is difficult to put a cost on loss of life, pain, suffering, loss of body image, loss of wages, stress on personal relationships, etc., secondary to the healthcare associated condition(s) related to medical error(s).

From these studies and generalized concern of healthcare providers, several standardized protocols were developed and implemented by many providers with significant reductions in avoidable adverse events. Examples of these protocols include “time out” in surgery to reduce wrong site/wrong patient surgeries and central line insertion to reduce CLABSI (Central Line-associated Bloodstream Infections). Several providers have implemented a return to basics approach in the provision of nursing care that has greatly reduced the development of pressure ulcers.

The public is bombarded with media coverage of wrong site surgeries. The public considers these unfortunate medical errors as a shocking, totally unacceptable, and preventable. The September 2009 release from Premier Safety Institute reports that tools developed by Johns Hopkins and the Michigan Keystone project to standardize operating room briefings and debriefings were evaluated. These tools used during more than 37,000 briefings and debriefings had an average compliance rate of 76 – 95 percent. Almost 90 percent of the involved team members agreed that the tools were effective in the improvement of teamwork and communication.

CBSI (catheter – related bloodstream infection) were once considered inevitable in ICUs (Intensive Care Units) have been proved to be universally preventable. The April 2010 edition of “Nursing 2010” included the article, “Checklist helps reduce CBSI rate to near zero.” Michigan partnered with The Johns Hopkins University School of Medicine in Baltimore to adopt a statewide

standardized prevention program aimed at preventing CBSI. The program included an evidence-based, five-point checklist, education and standardized supply carts. The program required and empowered each healthcare team member to issue a “stop now” – if any checklist item was not followed. Staff questioned doctors who didn’t wash their hands or use the checklist appropriately. Eighteen months after initiation, most Michigan ICUs reported that no CBSIs had occurred. Three years later, the rate remained at zero for participating ICUs.

In many cases, prevention of avoidable situations requires minimal effort and planning. However, there is no “Easy” button that guarantees preventable and avoidable issues will not happen. Risk Management should play a key proactive role in identifying areas of concern to minimize the possibilities of avoidable injury and harm.

Attitude and perception play a major role in risk management. “If we haven’t been taught to do no harm, we see no harm in doing harm. We cause harm and shrug it off. We cause harm and laugh about it. We cause harm and brag about it.” (The Do No Harm web site) Unfortunately, this appears to be the attitude of some providers, whether from lack of training, conditioning or apathy. These are the staff members who have little or no regard for the welfare of the patients, their peers, and often, themselves.

With some providers it is more subtle. Short staffing, mandatory overtime, equipment purchases based solely on cost become the norm, rather than the exception. These are the providers that have lost touch with the mission of healthcare. Their focus is often more on profits than the provision of quality care. Many view staff and patients as a disposable commodity.

Administration, including those involved directly in risk management, has both a responsibility and an opportunity to set the tone for the facility. Will it be proactive or reactive? Nurturing or punitive? Will areas of concern be ignored and swept under the carpet hoping no one will ever know?

Benjamin Franklin said, “An ounce of prevention is worth a pound of cure.” This quote applies to risk management. Properly applied, risk management will be more proactive (prevention) than reactive (damage control/corrective action striving for a cure).

In a nurturing setting, consequences are given fairly and justly (“just” culture) when behavior does not meet standards of practice and/or facility standards. Nurturing is defined as to “nourish,” “educate,” and “train.” Proactivity and nurturing go hand in hand to create the best environment for the delivery of the highest quality of care possible. Nurturing should not be only for staff, but also for patients and their significant others.

Risk is not totally eliminated in the best of environments, but potential for adverse events is reduced when everyone is working together proactively to prevent avoidable occurrences. In the ideal setting, staff/patient/significant other will be alert to potential areas of concern and would report those concerns for evaluation and possible action to prevent occurrence. Incidents that do occur will more likely be “near misses” caught by the safeguarding system(s) or incidents that cause little or no harm to the patient(s).

Facilities would not dismiss small problems, leaving them uncorrected with the potential of becoming expensive and possibly deadly. Staff/patient/significant other would be empowered to report and expect corrective action when concerns are identified. If NASA managers had addressed the flawed O-rings, the space shuttle Challenger disaster could have been prevented in

1986. The managers disregarded the engineers' warnings, and seven people lost their lives because of a faulty O-ring valued at less than a dollar! What a hard way to learn the valuable lesson of the importance of proactive prevention.

To complete the risk management process effectively, takes caring and courage. Coretta Scott King said, "It doesn't matter how strong your opinions are. If you don't use your power for positive change, you are, indeed, part of the problem." Mark Twain stated, "The secret of getting ahead is getting started. The secret of getting started is breaking your complex overwhelming tasks into small manageable tasks, and then starting on the first one." Both quotations apply to proactive risk management. No one wants to have a "Challenger disaster" at their facility.

In many hospitals, nurses are working with patients (nurturing) to help themselves to adopt healthier life styles. This includes empowering the patient to set their own schedules and question staff regarding hand washing and treatment rationale. Staff offer support to promote success, listen to the patient and significant others, and provide teaching and training at a level that the patient and their significant others can understand.

In a September 23, 2009, US News article, "The Doctor Can Understand You Now," USC computer scientist, communication specialists, and healthcare professionals are working on reasonably priced effective speech-to-speech translation system for use in clinics, emergency rooms and ambulance – where seconds often count. The group is initially focusing on translation between English and Spanish and hopes to deliver a working prototype within a four-year window.

In September 2008 at a CMS (Centers for Medicare and Medicaid Services) sponsored Midwest Consortium meeting *Leading the Path to Collaboration: Pressure Ulcer Prevention and Care*, an identified goal was the establishment of a committee of stakeholders to promote collaborative efforts to reduce the prevalence of pressure sores. On 11/3/08, the Pressure Ulcer Collaboration was established in Kansas. Representatives from the full spectrum of pressure ulcer care and prevention were invited to join the Collaborative. These included consumers, providers of all types, affiliated associations, and regulatory agencies. Many of those invited are now participating in the Collaboration. The Collaboration's goal is to develop and promote tools and resources that will improve communication and facilitate pressure ulcer prevention and treatment at all levels of care. The Risk Management Specialist participates in this Collaboration and is also a member of the Care Transition Team sub-committee.

In October 2009, the Risk Management Specialist represented Kansas at the initial meeting convened by the National Quality Forum to aide in establishing healthcare related standards of practice for patient safety. This on-going activity continues via periodic conference calls and face-to-face meetings with risk management representatives from most of the states.

Also starting in October 2009, the Risk Management Specialist joined others in Kansas on the HAI (Healthcare-associated Infection) Elimination Advisory Group to address the national priority to reduce HAIs. The group developed and submitted a plan to reduce HAIs, set 2-year, 3-year, 4-year and 5-year goals, and identified measures to be monitored.

While Kansas is ahead of many states because our risk management program has been in place for more than 20 years, there is always room for improvement. The current risk management regulations continue to be under review by KDHE (Kansas Department of Health and Environment) and provider affiliated agencies, organizations and associations, for possible revision. Many

aspects of patient safety and “just culture” are being considered for inclusion. Everyone wants to be in a safe environment and be treated justly.

Perception is crucial. Carl W Buechner said, “People are concerned not by things but by the view they take of them. They may forget what you said, but they’ll never forget how you made them feel.” This concept plays a vital role in risk management.

The September 2009 release from Premier Safety Institute reports that patients file malpractice lawsuits due to poor customer service – communication, honesty, accountability – after a perceived error. Many found that a lawsuit was the only way to find out what actually happened to them or a loved one. When open communication and honesty with patients and an apology occurred following medical errors, malpractice claims were reduced by as much as 55 percent.

Members from KARQM (Kansas Association of Quality and Risk Managers) and KHA (Kansas Hospital Association) continue to meet with KDHE in order to improve communication between these entities in regard to the risk management process. Our goal is to continue an open dialogue so we may learn from each other and improve the quality of care in Kansas medical care facilities.

KDHE publishes an annual report with aggregate data collected from the risk management quarterly reports, but these results cannot establish a system to enhance quality improvement. Only the facility can develop and implement such systems. The quarterly report form includes a section for medical care facilities to document systematic changes they have implemented to improve patient care and minimize the occurrences of medical errors. Approximately 15 % of the facilities completed this part of the quarterly report during 2009.

The book To Err is Human, written by the Institute of Medicine in 1999, emphasized that the medical field will never be able to completely stop medical errors, as the staff that order, prepare and administer the care are human and humans do make mistakes. But it is very clear that **if** we improve the processes of ordering, preparing and administering care, these improvements will assist us “humans” from making some of these errors. Should there ever be a wrong site surgery? No - not if a process is in place and properly implemented that would prevent anyone from operating on the wrong limb or the wrong eye. Pre-operative surgical site designation and “time out” for site, patient and procedure identification has become the standard. Yet in Kansas, we continue to have wrong site surgeries reported. The primary root causes, found during investigation, are provider’s failure to properly implement the protocols, confusion about the methods for site designation, and some facilities do not utilize the “time out” protocol at all.

It has been 20 years since this book was published, but the book continues to a quoted resource. Improvements have been made, but we are not there yet. We must find a better way to communicate potential problem areas and encourage medical care facilities to implement safer practices – “an ounce of prevention.” Staff, patients and families must be empowered. Patient safety must be put first above egos and personal agendas. Many facilities are striving for excellence. The Just Culture and Patient Safety First protocols continue to be steps in the right direction.

Because the definition for an adverse event is not universal it is impossible to compare data from state to state. The definition for adverse or a sentinel event from the Joint Commission on Accreditation of Healthcare Organization is “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb

or function.” Some states have adopted “never” events. Colorado’s definition is “All deaths arising from unexplained causes or under suspicious circumstances. Brain and spinal cord injuries. Life-threatening complications of anesthesia. Life-threatening transfusion errors or reactions. Burns; missing persons; physical, sexual, and verbal abuse; neglect; misappropriation of property; diverted drugs; malfunction or misuse of equipment.” New York’s definition is “An unintended adverse and undesirable development in an individual patient’s condition occurring in a hospital.” A list of 36 occurrences (reduced from 47) that must be reported follows the definition. New York has had this mandatory reporting for more than 20 years, and many from that state voice frustration that they have not moved beyond data gathering to actual evaluation and corrective action to prevent reoccurrence.

In Kansas, a reportable adverse event includes all occurrences when the standard of care was not met and injury occurred or was probable. Kansas’s adverse events also include incidents that were possible grounds for disciplinary action by the appropriate licensing agency of the involved individual, such as, unprofessional conduct. Many of the adverse events reported in Kansas, would not be reported to these other entities. One goal of the ongoing meetings with the National Quality Forum is to develop standardized terminology to facilitate state-to-state comparison, development of standards to address these common concern areas, and aide states in developing effective programs to reduce the patient safety risks.

Even with the best of the best, things do not always go as planned and hoped. In Kansas, our risk management is confidential and privileged. Providers are given an opportunity to candidly evaluate the event through risk management and make corrective action as warranted. We are seeing improvements and proactive prevention in many of our Kansas facilities.

Brief History of Kansas Risk Management

This report represents the twenty-first in a series written by KDHE staff. The report outlines the issues, problems, findings, and significant changes which have occurred in the implementation of the Kansas Risk Management law (KSA 65-4921 et. Seq.). In 1987, House Bill 2661 passed requiring every medical care facility in Kansas to establish an internal risk management program. On September 1, 1987, Bill Rein was named as the Director of Quality Assurance and Risk Management to provide oversight for the new legislative mandate. In 1988, risk management surveys began with annual surveys of 160 facilities by two Risk Management Specialists.

In 1996 following passage of House Bill 2867, combination licensure and risk management surveys for all non-accredited hospitals and ASCs (Ambulatory Surgical Centers) were initiated to assure compliance. Two Risk Management Specialists surveyed the 187 facilities at least every three years. In late 2008, KDHE began completing some Risk Management surveys at a later date than the routine survey of the facility. This action reduced the ability to review areas of concern identified in the routine survey during the risk management survey, per the KDHE protocol for a combination survey. However, benefits have greatly outweighed any disadvantages. Primary benefits for a risk management focused survey were the potential for a more accurate evaluation of a facility’s risk management program and a much greater opportunity for the provision of risk management education, when indicated.

The 1997 article, entitled “The Kansas Risk Management Program: What Has Changed and What Remains the Same,” explored the changes and early implementation efforts brought on by

passage of House Bill 2867. That article explained the conceptual process of incorporating risk management laws and statutes with existing state licensure regulations into a revised “standards review” which had not been conducted in a number of years. A limitation on similar Medicare surveys was a result of revised federal funding priorities. The article presented the philosophy and development of a new survey instrument, a summary of the types and frequency of deficiencies cited during the initial reviews, as well as statistics historically gathered on risk management reporting to licensing agencies.

New risk management statutes were passed in 1997 that included peer review and designated reports, records, and proceedings as confidential and privileged. On February 27, 1998, new risk management regulations became effective to enforce the new statutes. The January 1999 article, entitled “Two Years of Experience and Lessons Learned” reviewed the new regulations. The regulations were designed to reflect what had become recognized as the basic standards for risk management programs across the state.

“Striving for a Better Tomorrow,” submitted in 2000, reviewed the survey process for 1998 and 1999. The role of the medical facility surveyor continued to be primarily that of a regulator but also increased as an educator to hospitals and ambulatory surgical centers concerning the protection of risk management information, the need of the risk managers to become more proactive with observation and record review to ascertain possible risk management problems, and for risk managers to become more involved with minimizing patient adverse events.

“To Error is Human, BUT can be Deadly” (submitted in 2001) reviewed the risk management program for calendar year 2000. There was an increase in the government and the public’s awareness of medical errors with a demand that something must be done to protect patients from medical errors. The emphasis is placed on improving processes in order to minimize occurrences.

“Creating a Safer Health Environment,” (submitted in 2002) outlined the categories that states are using to develop risk management programs. The categories were established as criteria to be included in the development of the state programs.

While Kansas has accomplished most of these steps, the last step – enhancing/sustaining quality improvement - continues to be one that is most difficult to accomplish. One of the recommendations for completing this step is that states establish a coalition for the prevention of medical errors. The coalition would determine approaches for alerting and informing facilities about the risk of errors and develop practices for addressing identified problems. The states that have established this coalition have done so with members from all licensing agencies involved with the prevention of medical errors. Members from KARQM and KHA meet with KDHE in order to improve communication between these organizations/agencies in regard to the risk management process. (Starting in 2009, the Risk Management Specialist met periodically with peers from other states during the National Quality Forum patient safety conferences with a goal to develop protocols to improve patient safety.)

“Reduction of Preventable Errors – A Mandate, Not an Option” (submitted for 2003) stressed the high toll from hospital errors. On July 28, 2004, the National Academy for State Health Policy released a bulletin entitled, “Higher toll cited from hospital errors,” by Scott Allen, Globe Staff. The article identified medical mistakes as the third-leading cause of death in the United States, behind heart disease and cancer. The article quoted Dr Samantha Collier, vice president of medical affairs at HealthGrades, which publishes rankings of hospitals and doctors. According to Dr

Collier, “There is little evidence that patient safety has improved in the last five years.” “The equivalent of 390 jumbo jets full of people are dying each year due to likely preventable, in-hospital medical errors, making this one of the leading killers in the US.” The analysis used a broad definition of medical error. The definition changed to include cases in which hospital staff failed to respond quickly to signs of infection or other dangerous problems accounted for almost the entire increase in the number of deaths. The group noted that the increase in deaths came almost entirely from adding “failure to rescue” the patient as a medical error.

HealthGrades identified 195,000 deaths annually from 2000 - 2002 and estimated that Americans paid an extra \$19 billion in medical costs for the victims of these mistakes. Studies repeatedly showed that medical errors were widespread and harmed up to one in every 25 patients admitted to the hospital.

Many hospitals now have “rescue” teams that are activated whenever a patient’s status changes or fails to improve. These teams are empowered to “take charge” of the patient’s care, if indicated.

“Effective Risk Management” (submitted for 2004) emphasized the importance of a proactive risk management program. According to an April 2005 AARP (American Association of Retired Persons) bulletin, only 10% of the 84% of physicians who observed co-workers taking shortcuts, that could be dangerous to patients, reported what they saw. Additionally, infection control continued to be an on-going challenge. A March 2005 RN magazine article, “VAP Prevention, the latest guidelines,” stressed the risk to patient on mechanical ventilation and reported that one-third of the patients who develop VAP die. This article emphasized that the key to prevention is prevention of cross contamination, by appropriate gloving and gowning and washing hands with soap and water or alcohol-based antiseptic hand rub before and after contact.

“Putting the Patient’s Safety First” (submitted for 2005) focused on the benefits and obstacles of implementing Just Culture and Patient Safety First protocols. Many facilities have mission statements including the provision of ultimate care to all patients. These statements often come with many unwritten “ifs” – if staff has time, if it doesn’t cost too much, if it won’t upset the surgeon, if ... If your care is impacted by unwritten “ifs,” the facility should evaluate priorities and give patient care and patient safety it’s rightful place.

“The Triumphs and Challenges of Emergency Medicine” (submitted for 2006) spot lighted emergency medicine’s progress and shortcomings. On 6/13/07 an Associated Press release entitled “Woman dies in ER lobby as 911 refuses to help” stunned all who heard or read the release. The common questions were “What went wrong?” and “How could this happen?” We still don’t have all the answers, but many hospitals have taken corrective action, as a result of this death.

“Managing Medical Technology and Other Risk Management Challenges” (submitted for 2007) addressed the rapid development of medical technology and the challenges related to these changes. Staff are responsible for not only the patient, but also the equipment. Patients occasionally report that the only time staff touched them or spoke to them was purely in the course of performing a task. No matter how sophisticated technology has become, it has not be able to replicate the human touch. Technology coupled with human expertise are a winning combination benefiting both recipients and healthcare providers.

“Life Happens!” (submitted for 2008) described the human factors of risk management. Life is full of accomplishments, plateaus, and challenges. Sometimes things happen so rapidly that we do well just to “hang on” and keeping up with the changes is never ending. Life happens!

As challenges mount, ability to provide services meeting standards of practice (or at all), let alone exceeding standards to reach facility goals, may seem impossible. Staff, on all levels, may become frustrated as they find themselves unable to keep up with perceived or mandated job responsibilities.

Ambulatory Surgical Centers

Based on many factors, CMS determined that ASCs (Ambulatory Surgery Centers) required expansion of regulatory oversight. These factors included:

- 1) More than 38 percent increase in number of ASCs during the period of 2002 – 2007
- 2) Fifteen percent of ASCs surveyed in FY (Fiscal Year) 2008 had serious (condition-level) deficient practices
- 3) Hepatitis C outbreak in Nevada during CY (Calendar Year) 2008 traced to poor infection control practices in two ASCs. More than 50,000 former patients were notified of potential exposure and reportedly more than 100 people developed Hepatitis C as a result of their exposure in the ASCs
- 4) Subsequent surveys of Nevada ASCs found 64 percent had serious problems, primarily in infection control

These findings lead to development and pilot testing in 2008 (by three states - Maryland, Oklahoma, and North Carolina) of a new infection control survey instrument and use of tracer methodology (following at least one patient through the entire course of their ASC experience). Of the 68 ASCs surveyed during the pilot testing, approximately 19 percent had condition-level deficiencies and 85 percent had standard-level deficiencies, primarily in the area of infection control. Common deficient practice included use of single-dose medication vials for multiple patients, improper sterilization practices, general disinfection, sanitation, and failure to have a system for reporting notifiable disease to their respective State health agency.

Findings did not go unheeded. Actions were taken by the Federal government that became effective in 2009. Kansas was one of the first twelve states to apply the new protocols in 2009. KDHE implemented a revised ASC certification and licensure survey process using the revised federal survey process. The new survey process increased survey time, required additional surveyor ASC training, and increased survey rates in 2010 to 33 percent.

In FY 2009, CMS mandated that the states:

- 1) complete ASC surveys for 10% of the state’s non-accredited ASCs each year for compliance with federal regulations;
- 2) complete ASC validation surveys for 5% of the state’s accredited ASCs each year,
- 3) complete additional surveys to insure that no more than seven years elapses between surveys of any one ASC provider;
- 4) ensure that all ASC providers are surveyed at least every six years, on average; and

As medical care changes and the need to stay overnight after surgery becomes less prevalent, the number of ASCs continues to grow. In 1987, there were eight ASCs licensed in the state of Kansas. As of December 31, 2009, there were sixty-seven ASCs.

Acute Care and Critical Access Hospitals

Implementation of the new combined licensure/survey process for medical care facilities began on December 1, 1996. The goal was to survey each hospital at least every two and a half to three years. In 2000, federal certification requirements for resurveys in non-accredited hospitals were increased from 5% to 33% each year. Since many of the regulations are similar, the federal certification resurvey and licensure processes were combined to meet the increased workload. In FY 2009, CMS mandated that the states:

- 1) complete targeted surveys each year for compliance with federal regulations and ensure that no more than five years elapses between surveys for any one particular non-accredited hospital or non-accredited critical access hospital for not less than 5% of each of the two types of hospitals;
- 2) complete additional surveys to insure that no more than 4.5 years elapses between surveys of any one particular non-accredited hospital or non-accredited critical access hospital; and
- 3) ensure that all non-accredited hospital or non-accredited critical access hospital are surveyed at least every three years, on average.

As of December 31, 2009, Kansas had 71 licensed hospitals that were not designated as CAHs. Kansas continues to lead the states in the number of CAHs. As of December 31, 2009, there were 83 Critical Access Hospitals in Kansas. Converting to a CAH has not demonstrated any changes in the risk management outcomes. Hopefully, the supporting hospitals will continue to assist the CAHs in developing proactive and effective risk management and quality improvement programs. The goal is for these developments to lead to an overall improvement in patient safety and quality of care.

Risk Management Issues

Confidentiality of Risk Management information continues to be at the forefront of discussions between risk managers and associated organizations. Confidentiality concerns are associated with the Adams vs. St. Francis Regional Medical Center's decision of releasing the relevant facts and the Unzueta vs. Schalansky decision when the plaintiff's attorney was given access to all of the risk management investigational interviews of witnesses, both staff and patients. Although the mental impressions, decision-making processes, and conclusions of hospital personnel involved in the risk management or peer review processes continue to be protected, there is concern from risk managers that this may change in the future.

The Director of Medical Facilities and the Risk Management Specialist met with members of members of KARQM and KHA in 2001 to discuss risk management concerns. This group continues to meet on an ongoing basis to work on developing meaningful interpretations of these definitions. The goals of the meetings are to ensure a more universal reporting system for Kansas and to improve communication between associations and organizations that play a part in the risk management process.

Surveyors answer risk management questions during the risk management survey process. On an on-going basis, the Risk Management Specialist is available to provide education and answer questions for the medical care facilities. Many Kansas facilities had a changeover of risk managers during the interim between surveys. Per survey findings and as reported by risk management staff, some new and experienced risk managers fail to protect the reporter's name, to assure that risk management information is secured at all times, and/or to take immediate action when an error occurs. These risk managers do not investigate "near misses" and/or identifying root causes to pinpoint effective interventions, including improved processes, to further minimize occurrences. The risk management surveyors evaluate the facilities for compliance with the Kansas Risk Management statutes and regulations and with implementation of an effective risk management program.

Risk management regulation KAR 28-52-4 mandates that facilities assign a separate standard of care for each involved provider, and each issue. Finding the individual providers involved with the incident and determining a standard of care for those providers has been the focus of risk management for many years. Beginning in 2000, we saw a trend by facilities to place an emphasis on looking at the process of care not just the individuals involved. This does not mean that the risk management committees can discontinue reviewing individuals involved in the adverse event and assigning the individuals a standard of care. The trend of looking at the process as well as the individual is encouraged by KDHE. Frequently, the root cause is a process problem that precipitated staff's substandard performance. Assessing the process and making improvements on those processes demonstrates a proactive approach to minimizing future occurrences. As the Institute of Medicine Committee on Quality of Health Care in America reports in the book To Err is Human: Building a Safer Health System (1999), people in all lines of work make errors. Errors **can be prevented** by designing systems that make it harder for people to do the wrong thing and easier for people to do the right thing. This is also stressed in all "Patient Safety First" applications. We need to build safer systems by designing processes of care that will ensure that patients are safe from accidental injury.

The Risk Management Specialist

The KDHE's Risk Management Specialist is involved in many risk management activities. Those activities included, but were not limited to:

- 1) Review and approval of new and amended risk management plans;
- 2) Response to inquiries about state and federal regulations and the risk management process;
- 3) Review of adverse events and their corrective action as reported by facilities;
- 4) Review of facilities' quarterly reports;
- 5) Education of new facility applicants of risk management requirements;
- 6) Provision of consultation and presentation of workshops and training to risk managers and hospital personnel throughout the state;
- 7) Provision of consultation and training to KDHE surveyors;
- 8) On-site surveys; and
- 9) Creation of the annual risk management report.

The turnover of risk managers throughout the state continues and many are placed in their positions without training or orientation. In 2009, the Risk Management Specialist provided

educational programs for medical care facilities throughout the state, both in a group setting and on an individual basis.

Medical Facility Survey Process

Each hospital should anticipate that the survey process takes approximately one week to complete. An ASC survey, depending on size, will take approximately three to four days, with incorporation of the revised federal survey process. When deficiencies are cited, the facility may receive a revisit within six months. A survey revisit is usually accomplished in four to eight hours. In 2209, the average risk management survey included six hours of on-site survey time.

Citing a Deficiency

During the survey process, surveyors observe care provided to patients, review medical records for appropriate documentation, review facility policies for the required elements, conduct patient, family and/or staff interviews, and observe the physical environment of the facility. During the survey if the surveyor identifies that the facility's practice is not consistent with the regulatory requirement, a deficiency is written at the appropriate regulatory code/tag.

In order to assure that facilities are not cited twice for the same deficiency, surveyors will cite only the federal regulation if the deficient practice violates both state and federal requirements. There are no regulations for risk management in the federal regulations. Due to confidentiality, all risk management deficiencies are cited on a separate state deficiency statement.

Risk Management Goals for 2010

The Bureau of Health Facilities Risk Management continuous goals are to:

- Assist facilities in improving the risk management process through educational programs and consultation;
- Share information accumulated from literature, the direct involvement with other states and the direct involvement with federal coalitions/organizations;
- Monitor facility risk management programs through the survey process;
- Improve communication between state licensing agencies concerning specific cases.

KDHE believes that it is important to maintain and improve communication between licensing agencies, medical care facilities, and professional organizations in order to reach these goals. Questions related to the medical care facilities' licensure and/or risk management may be directed to:

Lynn Searles RN, Risk Management Specialist or
Charles Moore, Director of Medical Facilities and Survey Support
Bureau of Child Care and Health Facilities
Kansas Department of Health and Environment
1000 SW Jackson, Suite 200
Topeka, Kansas 66612-1365

Statistical Information

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Risk Management/Licensure and Certification

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Glossary of Terms

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Appendices

Frequently Cited Tags

Glossary of Terms

AHRQ	Agency for Healthcare Research and Quality
ASC	Ambulatory Surgical Center
BCCHF	Bureau of Child Care and Health Facilities
CAH	Critical Access Hospital
CBSI	Catheter-related Blood Stream Infections
CDC	Centers for Disease Control
CFR	Code of Federal Regulations
CLABSI	Central Line-associated Bloodstream Infections
CMS	Centers for Medicare and Medicaid Services
CY	Calendar Year
FY	Fiscal Year
HAI	Healthcare Associated Infection
ICU	Intensive Care Unit
KAR	Kansas Administrative Regulations
KARQM	Kansas Association of Quality and Risk Managers
KDHE	Kansas Department of Health and Environment
KHA	Kansas Hospital Association
KSA	Kansas Statutes Annotated
KSBHA	Kansas State Board of Healing Arts
KSBN	Kansas State Board of Nursing
KSPB	Kansas State Pharmacy Board
MDS	Minimum Data Set
NASA	National Aeronautics and Space Administration
NASHP	National Academy for State Health Policy
NCPS	National Center for Patient Safety
SB MDS	Swing Bed Minimum Data Set
SOC	Standard of Care
TAGS	(Survey Reference)

Tables Introduction

Historically data has been presented to medical care facilities related to the number of incidents confirmed to meet standard of care determination levels 3 or 4, the agency to which the incident was reported, and the number of reports generated by facility size. These figures are updated through the end of 2008 and are presented in the following tables.

Table 1*
Comparison of Reportable Incidents By Year and By Licensing Agency 2001 – 2009

Year	Total # of Reportable SOCs	SOC III	SOC IV	KSBHA	KSBN	KDHE	KBP	Other
2001	436	320	116	48 (11%)	208 (48%)	149 (34%)	14 (3%)	17 (4%)
2002	501*	395	106	57 (12%)	222 (47%)	149 (34%)	14 (3%)	16 (3%)
2003	572***	447	126	22 (16.1%)	43 (31.4%)	62 (45.3%)	8 (5.8%)	2 (1.4%)
2004	519****	388	131	61 (11.3%)	233 (43%)	219 (40.4%)	10 (1.8%)	19 (3.5%)
2005	640****	371	269	44 (6.9%)	339 (53%)	219 (34.2%)	22 (3.4%)	16 (2.5%)
2006	531*****	427	104	68 (12.8%)	243 (45.8%)	166 (31.3%)	32 (6%)	22 (4.1%)
2007	548*****	412	136	71 (13%)	249 (45.4%)	196 (35.8%)	18 (3.3%)	14 (2.5%)
2008	703*****	532	171	59 (8.4%)	401 (57%)	214 (30.5%)	14 (2%)	15 (2.1%)
2009	608*****	460	148	50 (8.2%)	407 (66.9%)	136 (22.3%)	8 (1.3%)	8 (1.3%)

***Table 1** above depicts the number of incidents reported to licensing agencies for the years 2001-2008. .

**The 2002 total number of SOCs by all providers was 93,627 with 501 SOC IIIs and SOC IVs or .535%.

***The 2003 total number of SOCs by all providers was 87,359 with 572 SOC IIIs and SOC IVs or .655%, an increase.

****The 2004 total number of SOCs by all providers was 89,306 with 519 SOC IIIs and SOC IVs or .581%, a decline.

****The 2005 total number of SOCs by all providers was 96,726 with 640 SOC IIIs and SOC IVs or .66%, an increase.

*****The 2006 total number of SOCs by all providers was 107,293 with 631 SOC IIIs and SOC IVs or .485%, a decline.

*****The 2007 total number of SOCs by all providers was 101,447 with 548 SOC IIIs and SOC IVs or .54%, an increase.

*****The 2008 total number of SOCs by all providers was 109,072 with 703 SOC IIIs and SOC IVs or .645%, an increase.

*****The 2009 total number of SOCs by all providers was 132,534 with 608 SOC IIIs and SOC IVs or .459%, a decline.

Table 2

Comparison of Total Number of **Reportable Incidents** Generated By Facility Size and Licensing Agency
2001-2009

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
1-25 beds	2009	5 (3.5%)	115 (79.8%)	22 (15.3%)	1 (0.7%)	1 (0.7%)
	2008	25 (17%)	84 (57.2%)	31 (21.1%)	3 (2%)	4 (2.7%)
	2007	16 (10.5%)	79 (51.9%)	48 (31.6%)	5 (3.3%)	4 (2.7%)
	2006	21 (12.1%)	61 (35.3%)	55 (31.8%)	15 (8.7%)	21 (12.1%)
	2005	16 (9.5%)	59 (34.9%)	89 (52.4%)	2 (1.2%)	3 (1.8%)
	2004	18 (14%)	40 (31%)	59 (46%)	1 (1%)	10 (8%)
	2003	19 (13.6%)	79 (56.5 %)	32 (22.8%)	8 (5.7%)	1 (1.4%)
	2002	6 (7%)	29 (32%)	53 (38%)	1 (1%)	3 (3%)
	2001	4 (5%)	36 (45%)	34 (42%)	1 (1%)	6 (7%)
26-50 beds	2009	0	20 (74.1%)	3 (11.1%)	2 (7.4%)	2 (7.4%)
	2008	2 (3%)	40 (60.7%)	22 (33.3%)	0	2 (3%)
	2007	15 (38.5%)	15 (38.5%)	9 (2.23%)	0	0
	2006	2 (6.5%)	16 (51.6%)	1 (3.2%)	3 (9.7%)	9 (29%)
	2005	1 (3.3%)	20 (66.7%)	8 (26.7%)	0	1 (3.3%)
	2004	4 (6%)	29 (40%)	39 (54%)	0	0
	2003	23 (23.9%)	35 (38%)	28 (34.4%)	5 (5.4%)	1 (1%)
	2002	9 (13%)	38 (53%)	22 (31%)	3 (4%)	0
	2001	17 (24%)	36 (50%)	20 (28%)	3 (4%)	3 (4%)
51-100 beds	2009	18 (27.7%)	33 (50.8%)	13 (20%)	0	1 (1.5%)
	2008	3 (2.2%)	110 (82.1%)	18 (13.4%)	2 (1.5%)	1 (.8%)
	2007	5 (10.2%)	23 (51%)	12 (24.5%)	1 (2%)	5 (10.2%)
	2006	15 (22.4%)	44 (65.7%)	0	1 (1.5%)	7 (10.4%)
	2005	3 (3.9%)	41 (53.2%)	13 (16.9%)	16 (20.8%)	4 (5.2%)
	2004	5 (12%)	24 (56%)	7 (16%)	2 (5%)	5 (12%)
	2003	4 (11%)	17 (41.5%)	15 (36.6%)	0	2 (4.9%)
	2002	6 (9%)	25 (36%)	34 (49%)	2 (3%)	2 (3%)
	2001	4 (11%)	21 (54%)	9 (24%)	0	4 (11%)
101-200 beds	2009	7 (10.1%)	51 (73.9%)	9 (13%)	1 (1.5%)	1 (1.5%)
	2008	4 (26.7%)	5 (33.3%)	4 (26.7%)	0	1 (13.3%)

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
	2007	15 (25.9%)	29 (50%)	4 (6/9%)	9 (15.5%)	1 (1.7%)
	2006	13 (36.1%)	18 (50%)	1 (2.8%)	0	4 (11.1%)
	2005	4 (9.3%)	35 (81.4%)	2 (4.6%)	0	2 (4.6%)
	2004	18 (17%)	65 (65%)	21 (19%)	3 (3%)	1 (1%)
	2003	0	10 (52.6%)	9 (47.4%)	0	0
	2002	9 (17%)	36 (67%)	8 (15%)	1 (2%)	0
	2001	6 (11%)	38 (69%)	10 (18%)	0	1 (2%)
201+ beds	2009	11 (4.6%)	155 (64.6%)	68 (28.3%)	4 (1.7%)	2 (0.8%)
	2008	21 (6.3%)	160 (47.9%)	139 (41.6%)	8 (2.4%)	6 (1.8%)
	2007	16 (7%)	101 (41%)	122 (50%)	3 (1%)	3 (1%)
	2006	13 (6.5%)	96 (47.8%)	5 (2.5%)	6 (3%)	81 (40.3%)
	2005	18 (5.3%)	181 (57.8%)	104 (33.2%)	4 (1.3%)	6 (1.9%)
	2004	14 (10%)	2 (19%)	91 (65%)	4 (3%)	3 (2%)
	2003	19 (48.7%)	1 (2.5 %)	17 (41.5%)	1 (2.6%)	1 (2.6%)
	2002	13 (8%)	87 (50%)	59 (34%)	8 (5%)	6 (3%)
	2001	17 (9%)	85 (45%)	76 (40%)	10 (5%)	3 (1%)
ASCs	2009	2 (15.4%)	5 (38.5%)	6 (46.1%)	0	0
	2008	4(57.1%)	2 (28.6%)	0	1 (14.3%)	0
	2007	3 (43%)	0	3 (43%)	0	1 (14%)
	2006	4 (20%)	8 (40%)	0	1 (5%)	7 (35%)
	2005	2 (25%)	3 (37.5%)	3 (37.5%)	0	0
	2004	2 (29%)	3 (43%)	2 (28%)	0	0
	2003	0	0	0	0	0
	2002	1 (8%)	0	3 (23%)	0	9 (69%)
	2001	0	0	0	0	0

***Table 2**, compares the total number of incidents reported by facility size and licensing agency, including percentages of reports to agencies by facility size and year.

Table 3

Comparison of Average Number of Incidents Reviewed and Total Number of Reportable Incidents Filed By Facility Size 2005 – 2009

Facilities by Bed Size/ Category	Number of Facilities in Size Category 2008	Avg # of SOC's/ Total # of Reportable SOC's 2005	Avg # of SOC's/ Total # of Reportable SOC's 2006	Avg # of SOC's/ Total # of Reportable SOC's 2007	Avg # of SOC's/ Avg # of Reportable SOC's /Avg # of Incidents 2008	Avg # of SOC's/ Avg # of Reportable SOC's /Avg # of Incidents 2009
1 - 25	93	296.9/169	351/176	408.4/152	380.4/1.6/250.8	557.3/2.1/327.5
26 - 50	15	492.8/30	501.8/31	544.2/39	1329.4/5.1/942.8	515.4/1.8/358.5
51 - 100	23	555.8/77	596.8/67	524.9/49	615.3/5.7/586.3	603.8/2.8/515.9
101 - 200	12	703.4/43	1049/36	1221.5/58	517.2/1.2/447.1	1173.4/5.7/1037.7
200 +	13	2873/313	3044/201	2701/243	4661.3/25.7/3955.6	3263.8/18.5/3352.1
ASCs	67	39.6/8	37/20	34.8/7	35.6/10.8/24.7	37.5/0.19/26.4
Totals	223	469.5/640	506.1/531	501.9/548	620.2/3.2/481.3	591.6/2.7/473.1

***Table 3** above compares the average number of SOC determinations reviewed and the total number of SOC determinations reported, by facility size. The average number would equate to item number 4 on the Kansas Department of Health and Environment Confidential Quarterly Report form, while the total figure would represent item number 4 (c) and 4 (d) on the same form. The bed size is based on the acute bed count as determined by a facility's license. For example, a facility licensed for 20 acute beds and 60 long-term care beds would be included in the 1-25 bed grouping. Mental health, mental retardation, and psychiatric hospitals are listed by total bed count.

KDHE RISK MANAGEMENT ARTICLES

1. **"Risk Management Defined"** discusses the history of risk management enabling legislation (House Bill 2661). This article attempts to explain the purposes for requiring risk management programs, the elements necessary to meet statutory requirements, and plans for KDHE's first survey cycle. The article was written in 1988.
2. **"Health Care Risk Management in Kansas: 1990 Issues"** attempts to answer the eight most frequently asked questions about risk management laws during KDHE's first survey cycle. Those questions include: What is the essence of the risk management law? Why are hospital committees required to determine standards of care in individual cases? What is necessary to assure that standards of care are met? How must an investigation be accomplished to meet the requirements of state risk management laws? The article was written in 1989.
3. **"The Failures of Risk Management"** addresses the early problems faced by risk management programs. Those problems included administrative turnover, failure to document provider- and issue-specific standard of care determinations, lack of incident reporting logs sufficient to assure that each case received a standard of care determination, and lack of executive committee oversight. The article also discusses KDHE objectives for its third risk management survey cycle. This article was written in 1990.
4. **"A Statutory Approach to Hospital Risk Management: Five Years in Kansas"** reviews the history of risk management programs from 1987 to 1991. In addition, the article discusses the results of over 200 interviews with direct care staff concerning risk management program in 64 facilities. This article was written in 1991.
5. **"Five Years of Risk Management in Kansas: An Overview"** was published in The Kansas Nurse and provides an overview of the risk management program from a nursing perspective. The article was written in 1992.
6. **"Kansas Risk Management Laws: Report and Observations on the First Three Survey Cycles"** describes the survey cycles implemented by KDHE. Comparisons of incident reporting activities by aggregate facility size to types of licensing agencies are made. The article was written in 1993.
7. **"Resident Abuse, Neglect, and Exploitation and the Kansas Risk Management Law"** describes the role of the risk management law in relation to other federal and state statutes related to allegation of resident abuse in facilities. The article was written in 1994.
8. **"Compliance of Facilities with Kansas Risk Management Surveys: An Update"** provides statistics related to risk management activities from 1988 through 1993. The article was written in 1994.
9. **"Rationale: The Basis for Standard of Care Decisions"** explores the importance of developing clear and reasonable documentation in risk management investigations. The article was written in 1995.
10. **"The Kansas Risk Management Law: Does it need to be Redesigned for the Future?"** discusses the history of risk management in Kansas and its relationship to other quality assurance and quality improvement efforts. The article was written in 1995.
11. **"Final Risk Management Site Review Statistics through Survey Year VI"** provides an overview of compliance history and incident reporting during six risk management survey cycles. The article was written in 1996.

12. **“The Kansas Risk Management Program: What Has Changed and What Remains the Same”** describes the changes occurring in medical care facility licensure laws following passage of 1996 House Bill 2867. The implementation of a state licensure/risk management survey process is discussed and statistics from early surveys are presented. The article was written in 1997.
13. **“Two Years of Experience and Lessons Learned”** describes the experience of combining the licensure/risk management survey. Provides information on the Adams vs. St Francis court case, which opened up some of the facts of risk management. Introduced the new regulations, which were intended to provide further guidance to medical care facilities in implementing the provisions of KSA 65-4922. This article was written in 1999.
14. **“Striving for a Better Tomorrow”** describes the new role of the Risk Management Specialist, adding an educational component, the start of a new quarterly report, which would give corrective action for trending issues as well as the individual. This article was written 2001.
15. **“On-site Licensure/Risk Management Surveys: “To Error is Human” - BUT Can Be Deadly”** describes the change of focus from looking at only individuals involved with incidents to an emphasis of looking at the process of care. This does not mean that the risk management committees can discontinue reviewing the individuals involved in the adverse event, but the facility should also review the process involved. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. We need to build safer systems by designing processes of care to ensure that patients are safe from accidental injury. Patients need assurance that the process of care will proceed correctly and safely so they have the best chance possible of achieving desired outcomes. Written 2001.
16. **“Dirty Bed,”** by Michael J Berens for The Chicago Tribune, reported that dirty hospitals kill 75,000 patients a year, unnecessarily. The article noted 50% of the doctors and nurses in hospitals do not clean their hands between patients. The article was written in 2003.
17. **“Higher toll cited from hospital errors”** by Scott Allen, Globe staff. The article identified medical mistakes as the third-leading cause of death in the United States, behind heart disease and cancer. The article quoted Dr Samantha Collier, vice president of medical affairs at HealthGrades, which publishes rankings of hospitals and doctors. This article was written in 2004.
18. **“VAP Prevention, the latest guidelines,”** describes this type of pneumonia as a frequent complication of patients on ventilators for 48 hours or more. Up to one third of the patients developing VAP die. Prevention of cross contamination is paramount to preventing VAP. The article was written in 2005.
19. **“Errors Associated with Medications Removed from Automated Dispensing Machines Using Override Function,”** Hospital Pharmacy, reports on the problems and solutions related to staff overrides of these machines. The article was written in 2006.
20. **“Plague of Errors,”** by John Buntin, focuses on the cause and effect of rising hospital rates. With infection rates escalated by 36 % since 1975, approximately 5 % of hospital patients contract a nosocomial infection, each year that results in 90,000 deaths. The article was written in 2005.
21. **“Stamping out surgical site infections,”** RN Magazine, stress the impact of 500,000 surgical site infections annually in the US. Possible causes include failure to adhere to CDC guidelines for pre-operative antimicrobials with a reported 25 – 50 % misuse. The article was written in 2006.
22. **“Patients Have Better Outcomes in Most Wired Hospitals,”** by Debra Wood RN, NurseZone.com. Patients have better outcomes in “wired hospitals as hospitals turn to technology to assist with care. The article appeared in July 2007.

23. **“Parkland ER launches self-service check in,”** news release at Parkland Hospital website describes the innovative approach to improve management of emergency department patients. The article was released 6/20/07.
24. **“One-third of ED communications are interruptions, contributing to medical errors,”** by Brixey and colleges, in the *International Journal of Medical Informatics*, reported on a case study conducted in a Level One Trauma Center at a teaching hospital. The article appeared in June 2007.
25. **“Woman dies in ER lobby as 911 refuses to help”** was released by the Associated Press and related the events leading to the death of a 43 year-old woman in a hospital waiting area. The article was released on 6/13/07.
26. **“Technology: Friend or For?”** by David Harrington, PHD, discussed examples of what happens when entities embrace or fail to embrace cost cutting technology. Article released in December 2006.
27. **“Electronic Health Records: Useful Tools or High-Tech Headache?”** by Roxanne Nelson, BSN, RN, in the *American Journal of Nursing*, candidly spoke to the pros and cons of the electronic health record. Article appeared in March 2007.
28. **“Electronic Medical Records: Friend or Foe?”** by Patrick Romero. reported on President Bush’s 2014 goal for Electronic Medical Record usage and progress toward that goal. The article was released on 5/14/08.
29. **“Slim, Flexible Stents Approved to Treat Heart Disease,”** by Adam Voiland, describes the new generation of drug-coated stents. The article was released on 7/8/08.
30. **“Part 2: Bar-Coding & Implanting Humans Is Here,”** by Brenda Miller, in the *Edge*, reported on implantation uniquely identified GPS (Global Positioning System) devices in humans. The article appeared in September 2005.
31. **“RFID vs Medical Devices; Friend or Foe,”** by Dr Hazem El-Orady, spoke to the Dutch study published in the 6/25/08 Journal of American Medical Association. The article was released in The Medical Informatics Portal on 7/15/08.
32. **“Wireless Technology Friend or Foe?”** an undated brochure by the US Department of Homeland Security, educates the public on “rogue” wireless access and countermeasures.
33. **“When It’s Surgery, Don’t Get It Wrong,”** by Tracy Grant, in the Washington Post, relates a near miss experience and related research. The article appeared on 7/22/08.
34. **“Heparin Errors Continue Despite Prior, High-Profile, Fatal Events,”** in the *Institute for Safe Medication Practices*, reports on continuing problems in this area, including multiple errors in July 2008 in a Texas hospital. The article appeared on 7/17/08.
35. **“Never Fear Trying, Never Quit Caring,”** by Joe Tye, in *Spark Plug’s Weekend Spark*, encourages individuals to be courageous and do the right thing. The article appeared on 7/11/08.
36. **“For Want of A Nail Rhyme,”** Famous quotes UK and Rhymes.org.uk
37. **“Space Shuttle Challenger disaster,”** Wikipedia
38. **“American Recovery and Reinvestment Act of 2009 (Recovery Act) Ambulatory Surgical Center Healthcare-Associated Infection (ASC-HAI) Prevention Initiative,”** CMS S&C-09-43, 6/12/09

39. **"Primum non nocere,"** Wikipedia
40. **"Medical Errors Cost U.S. \$8.8 Billion, result in 238, 337 potentially preventable deaths, according to HealthGrades Study,"** HealthGrades article appeared on 4/8/08
41. **"Medicare to Cut Payments for Avoidable Errors,"** by Julie Rovner. Article appeared on 8/22/07.
42. **"Medicare Won't Pay for Medical Errors,"** by Kevin Sack. Article appeared in The New York Times on 10/1/08.
43. **"Medicare this week stops paying for the cost of preventable hospital errors,"** published 9/29/08 on Everything Cleveland.
44. **"THE DIRECT MEDICAL COSTS OF Healthcare-Associated infections in U.S. Hospitals and the Benefits of Prevention,"** CDC, March 2009
45. **"Pressure Ulcers and Wound Care,"** by Dr Richard Salcido MD and Adrian Popescu, MD, with the University of Pennsylvania School of Medicine. The updated 7/9/10 article appeared on eMedicine.
46. **Premier Safety Institute** release, 9/28/09
47. **"Checklist helps reduce CBSI rate to near zero,"** Nursing 2010, April 2010
48. **Do No Harm** quote, www.donoharm.us
49. **"The Doctor Can Understand You Now,"** US News, 9/23/09
50. **Carl W Buechner** quotes, Thinkexist.com

APPENDIX A

Total of Survey Codes Cited During 41 **Acute Care Hospital** Licensure/Certification Surveys 2009

SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES
H0010	1	A0147	2	A0207	1	A0450	10	A1132	1
H0042	1	A0148	1	A0208	1	A0454	1	A1533	1
H0044	1	A0154	1	A0214	3	A0463	1	A2400	2
H0063	1	A0159	1	A0263	3	A0469	1	A2407	1
H0114	1	A0166	2	A0265	1	A0490	1	A2411	1
		A0168	3	A0267	1	A0491	4		
		A0170	1	A0275	1	A0502	3		
A0043	2	A0171	1	A0338	1	A0505	3		
A0046	1	A0172	1	A0340	1	A0511	1		
A0049	1	A0174	1	A0341	1	A0630	1		
A0057	1	A0175	2	A0385	3	A0700	2		
A0084	1	A0176	1	A0386	3	A0701	5		
A0091	1	A0178	1	A0392	4	A0724	4		
A0115	2	A0182	1	A0395	5	A0747	3		
A0117	2	A0183	1	A0396	8	A0748	1		
A0118	1	A0184	1	A0397	2	A0749	8		
A0119	1	A0194	1	A0398	2	A0750	2		
A0123	1	A0196	2	A0404	3	A0756	1		
A0130	1	A0199	1	A0405	2	A0955	1		
A0133	1	A0200	1	A0409	4	A0958	1		
A0143	2	A0201	1	A0431	2	A1004	1		
A0144	4	A0202	1	A0438	2	A1076	1		
A0145	1	A0204	2	A0439	1	A1077	1		
A0146	1	A0205	1	A0442	3	A1079	2		

APPENDIX B

Total of Survey Codes Cited During 30 Critical Access Hospital Licensure and Certification Surveys 2009

SURVEY CODES	# of CITES	SURVEY CODES	# of CITES	SURVEY CODES	# of CITES	SURVEY CODES	# of CITES
H0010	2	C0204	1	C0301	1	C0335	1
H0063	1	C0211	1	C0302	4	C0336	1
H0138	1	C0220	1	C0304	3	C0337	1
		C0222	2	C0305	1	C0350	1
		C0225	5	C0306	1	C0361	1
		C0229	1	C0307	37	C0362	1
		C0240	1	C0308	6	C0368	2
		C0241	1	C0309	1	C0369	1
		C0270	2	C0320	2	C0370	2
		C0272	2	C0322	2	C0381	1
		C0276	7	C0323	1	C0385	6
		C0278	3	C0330	3	C0386	1
		C0280	1	C0331	5	C0388	1
		C0291	1	C0332	2	C0395	2
		C0295	1	C0333	6	C0396	1
		C0296	1	C0334	5	C0407	1
		C0297	2	C0335	3	C2400	3
		C0298	2	C0336	2	C2406	2
		C0300	1	C0337	1	C2407	1
		C0301	1	C0338	3		
		C0302	1	C0339	3		
		C0303	1	C0340	1		
		C0304	2	C0345	1		
		C0307	12	C0360	1		
		C0308	2	C0364	1		
		C0330	1	C0366	1		
		C0331	2	C0368	1		
		C0332	1	C0369	1		
		C0333	1	C0370	1		
		C0334	1	C0371	1		

APPENDIX C

Total of Survey Codes Cited During 23 **Ambulatory Surgical Center** Licensure and Certification Surveys
2009

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
S0105	1	S0685	1	Q0029	1
S0145	1	S0695	1	Q0030	1
S0150	1	S0700	1	Q0031	1
S0220	1	S0720	3	Q0033	1
S0300	1	S0725	1	Q0034	1
S0320	1	S0730	1	Q0040	1
S0340	1	S0735	1	Q0041	1
S0365	1	S0740	2	Q0043	1
S0370	1	S0835	1	Q0061	1
S0375	1			Q0105	3
S0405	1	Q0003	2	Q0106	1
S0455	1	Q0004	1	Q0161	1
S0550	1	Q0005	1	Q0162	1
S0555	1	Q0009	1	Q0180	1
S0560	2	Q0010	1	Q0181	4
S0575	5	Q0012	1	Q0182	2
S0580	1	Q0014	1	Q0221	2
S0590	1	Q0018	1	Q0223	1
S0595	1	Q0019	1	Q0224	2
S0620	1	Q0020	1	Q0240	1
S0625	1	Q0021	1	Q0241	2
S0650	1	Q0022	2	Q0242	1
S0655	2	Q0023	1	Q0243	1
S0680	1	Q0024	1	Q0245	1

APPENDIX D

Total of Survey Codes cited During 76 Hospital, CAH and ASC **Risk Management** Surveys 2009

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
R0800	2	R0813	3	R0830	1
R0801	5	R0819	1	R0831	1
R0802	4	R0820	2	R0832	3
R0805	1	R0825	1	R0833	19
R0807	4	R0826	1	R0835	1
R0808	1	R0828	1	R0837	1
R0811	1	R0829	2		

APPENDIX E

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 41 **Hospital_Certification & Licensure 2009**

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
A0450 – Medical Record Services	10	%
A0396 – Nursing Care Plan	8	%
A0749 – Infection Control Officer Responsibilities	8	%
A0701 – Maintenance of Physical Plant	5	%

APPENDIX F

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 30 **CAH Hospital Certification Surveys 2009**

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
C0307 - Record System	12	%
C0276 - Policies – Drug Management	7	%
C0385 - Patient Activities	6	%
C0225 - Maintenance	5	%

APPENDIX G

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 48 **Hospital & CAH** Risk Management Surveys 2009

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
R0833 – Separate SOC per provider and clinical issue	15	31.3%
R0801 – Risk Management plan approved and reviewed annually by the facility's governing body	5	10.4%
R0807 – Risk Management plan included name and address of the facility and name and title of the facility's risk manager	4	8.3%

APPENDIX H

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During **ASC** Surveys – 23 Certification & Licensure and 28 Risk Management Surveys 2009

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
Q0241 – Sanitary Environment	5	%
S0575 – Infection Control	5	%
R0833 - Separate SOC per provider and clinical issue	5	17.9%
Q0181 – Administration of Drugs	4	%
Q0105 – Emergency Equipment	3	%
S0720 - Ancillary Services	3	%

APPENDIX I

2009 Cited Survey Codes

State Licensure and Federal Certification Acute Care Hospital:

H0010 **KAR 28-34-3b(a)(10)** Each patient is informed of the facility's policies regarding patient rights during the admission process.

H0042 **KAR 28-34-8a(d)(3)** Personnel records. Accurate and complete personnel records shall be maintained for each employee. Personnel records shall contain at least the following information for each employee's records of the initial health examination and subsequent health services and periodic health evaluations.

H0044 **KAR 28-34-8a(f)** Personnel health requirements. Upon employment, all hospital personnel shall have a medical examination which shall consist of examinations appropriate to the duties of the employee, including a chest X-ray or tuberculin skin test. Subsequent medical examinations or health assessments shall be given periodically in accordance with hospital policies. Each hospital shall develop policies and procedures for control of communicable disease, including maintenance of immunization histories and the provision of educational materials for patient care staff.

H0063 **KAR 28-34-1a(d)** Pharmacy and therapeutics committee. Each hospital shall establish a pharmacy and therapeutics committee or its equivalent. The committee shall consist of at least physicians, nurses and pharmacists. This committee shall assist in the formulation of broad professional policies regarding evaluation, appraisal, selection, procurement, storage, distribution and use of drugs and safety procedures and all other matters relating to drugs in the hospital. This committee shall meet at least quarterly, record its proceedings and report to the medical staff.

H0138 **KAR 28-34-18a(f)** Perinatal committee. The hospital shall establish an obstetrical and newborn services committee to monitor, evaluate, and recommend the provision of patient services. The committee membership shall include appropriate medical and nursing staff personnel.

A0043 **CFR 482. 12** The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

A0046 **CFR 482. 12(a)(2)** [The governing body must] appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

A0049 **CFR 482.12(a)(5)** [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

A0057 **CFR 482.12(b)** The governing body must appoint a chief executive officer who is responsible for managing the hospital.

A0084 **CFR 482. 12(e)(1)** The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

- A0091 **CFR 482.12(f)** Emergency Services
- A0115 **CFR 482.13** A hospital must protect and promote each patient's rights.
- A0117 **CFR 482.13(a)(1)** A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.
- A0118 **CFR 482.13(a)(2)** The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.
- A0119 **CFR 482.13(a)(2)** The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.] The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.
- A0123 **CFR 482.13(a)(2)(iii)** At a minimum:
In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.
- A0130 **CFR 482.13(b)(1)** The patient has the right to participate in the development and implementation of his or her plan of care.
- A0133 **CFR 482.13(b)(4)** The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.
- A0143 **CFR 482.13(c)(1)** The patient has the right to personal privacy.
- A0144 **CFR 482.13(c)(2)** The patient has the right to receive care in a safe setting.
- A0145 **CFR 482.13(c)(3)** The patient has the right to be free from all forms of abuse or harassment.
- A0146 **CFR 482.13(d)** Patient Rights: Confidentiality of Records
- A0147 **CFR 482.13(d)(1)** The patient has the right to the confidentiality of his or her clinical records.
- A0148 **CFR 482.13(d)(2)** The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.
- A0154 **CFR 482.13(e)** Patient Rights: Restraint or Seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.
- A0159 **CFR 482.13(e)(1)(i)(A)** Patient Rights: Restraint or Seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation

by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

A0166 **CFR 482.13(e)(4)(i)** The use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care.

A0168 **CFR 482.13(e)(5)** The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

A0170 **CFR 482.13(e)(7)** The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

A0171 **CFR 482.13(e)(8)** [Unless superseded by State law that is more restrictive,] after 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

A0172 **CFR 482.13(e)(8)** [Unless superseded by State law that is more restrictive,] after 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

A0174 **CFR 482.13(e)(10)** The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

A0175 **CFR 482.13(e)(10)** The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

A0176 **CFR 482.13(e)(11)** Physician and other licensed independent practitioner training requirements must be specified in hospital policy.

A0178 **CFR 482.13(e)(12)** When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1-hour after the initiation of the intervention by a physician or other licensed independent practitioner; or registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.

A0182 **CFR 482.13(e)(14)** If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.

A0183 **CFR 482.13(e)(15)** All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored face-to-face by an assigned, trained staff member; or by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

A0184 **CFR 482.13(e)(16)** When restraint or seclusion is used, there must be documentation in the patient's medical record of the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior.

A0194 **CFR 482.13(f)** Restraint or Seclusion: Staff Training Requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.

A0196 **CFR 482.13(f)(1)** Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion-

- (i) Before performing any of the actions specified in this paragraph;
- (ii) As part of orientation; and
- (iii) Subsequently on a periodic basis consistent with hospital policy.

A0199 **CFR 482.13(f)(2)** Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

A0200 **CFR 482.13(f)(2)(ii)** Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

A0201 **CFR 482.13(f)(2)(iii)** [The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:]

- (iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

A0202 **CFR 482.13(f)(2)(iv)** [The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:]

- (iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).

A0204 **CFR 482.13(f)(v)** [The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:]

- (v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

A0205 **CFR 482.13(f)(2)(vi)** [The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least] monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.

A0214 **CFR 482.13(g)** Hospitals must report deaths associated with the use of seclusion or restraint.

A0263 **CFR 482.21** The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

A0265 **CFR 482.21(a)(1)** The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and

A0267 **CFR 482.21(a)(2)** The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.

A0275 **CFR 482.21(b)(2)(i)** The hospital must use the data collected to--
(i) Monitor the effectiveness and safety of service and quality of care.

A0338 **CFR 482.22** The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

A0340 **CFR 482.22(a)(1)** The medical staff must periodically conduct appraisals of its members.

A0341 **CFR 482.22(a)(2)** The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

A0385 **CFR 482.23** The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

A0386 **CFR 482.23(a)** The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

A0392 **CFR 482.23(b)** The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

A0395 **CFR 482.23(b)(3)** A registered nurse must supervise and evaluate the nursing care for each patient.

A0396 **CFR 482.23(b)(4)** The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

A0397 **CFR 482.23(b)(5)** A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

A0398 **CFR 482.23(b)(6)** Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing services.

A0404 **CFR 482.23(c)** Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

A0405 **CFR 482.23(c)(1)** All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

A0409 **CFR 482.23(c)(3)** Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

A0438 **CFR 482.24(b)** The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

A0439 **CFR 482.24(b)(1)** Medical records must be maintained in their original or legally reproduced form for a period of at least 5 years.

A0442 **CFR 482.24(b)(3)** [Information from or copies of records may be released only to authorized individuals,] and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.

A0450 **CFR 482.24(c)(1)** All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

A0454 **CFR 482.24(c)(2)** (i) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in paragraph (c)(1)(ii) of this section. (ii) For the 5 year period following January 26, 2007, all orders, including verbal orders, must be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to write orders by hospital policy in accordance with State law.

A0463 **CFR 482.24(c)(2)(ii)** [All records must document the following, as appropriate:]
Admitting diagnosis.

A0469 **CFR 482.24(c)(2)(viii)** [All records must document the following, as appropriate:]
Final diagnosis with completion of medical records within 30 days following discharge or outpatient care.

A0490 **CFR 482.25** The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area

under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

- A0491 **CFR 482.25(a)** The pharmacy or drug storage area must be administered in accordance with accepted professional principles.
- A0502 **CFR 482.25(b)(2)(i)** All drugs and biologicals must be kept in a secure area, and locked when appropriate.
- A0504 **CFR 482.25(b)(2)(iii)** Only authorized personnel may have access to locked areas.
- A0505 **CFR 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.
- A0511 **CFR 482.25(b)(9)** A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.
- A0553 **CFR 482.26(d)** Records of radiologic services must be maintained.
- A0630 **CFR 482.28(b)(2)** Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.
- A0700 **CFR 482.41** The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.
- A0701 **CFR 482.41(a)** The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.
- A0724 **CFR 482.41(c)(2)** Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
- A0747 **CFR 482.42** The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.
- A0748 **CFR 482.42(a)** A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.
- A0749 **CFR 482.42(a)(1)** The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.
- A0750 **CFR 482.42(a)(2)** The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.
- A0756 **CFR 482.42(b)** Standard: Responsibilities of chief executive officer, medical staff and director of nursing services. The chief executive officer, the medical staff, and the director of nursing must--
(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and
(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

- A0891 **CFR 482.45(a)(5)** [The hospital must have and implement written protocols that:] Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues.
- A0955 **CFR 482.51(b)(2)** A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.
- A0958 **CFR 482.51(b)(5)** The operating room register must be complete and up to date.
- A1004 **CFR 482.52(b)(2)** [The policies must ensure that the following are provided for each patient:] An intraoperative anesthesia record.
- A1076 **CFR 482.54** If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.
- A1077 **CFR 482.54(e)** Outpatient services must be appropriately organized and integrated with inpatient services.
- A1079 **CFR 482.54(b)** The hospital must assign an individual to be responsible for outpatient services; and have appropriate professional and nonprofessional personnel available.
- A1132 **CFR 482.56(b)** Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.
- A1533 **CFR 482.66(b)(3)** If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.
- A2400 **CFR 489.20(l)** The provider agrees, in the case of a hospital as defined in §489.24(b), to comply with §489.24.
- A2407 **CFR 489.24(d)(1-3)** (1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either-
- (i) within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.
 - (ii) For transfer of the individual to another medical facility in accordance with paragraph (e) of this section.
- (2) Exception: Application to inpatients.
- (i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual
 - (ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.
 - (iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.
- (3) Refusal to consent to treatment.
- A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not

consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

A2411 **CFR 489.24 (f)** A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers, which, for purposes of this subpart, means hospitals meeting the requirements of referral centers found at §412.96 of this chapter) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department.

Federal Certification Critical Access Hospitals:

C0202 **CFR 485.618(b)** Equipment, supplies and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

C0204 **CFR 485.618(b)(2)** [The items available must include the following:]

Equipment and supplies commonly used in life saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

C0211 **CFR 485.620(a)** Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

C0220 **CFR 485.623** Physical Plant and Environment

C0222 **CFR 485.623(b)(1)** The CAH has housekeeping and preventive maintenance programs to ensure that-

(1) all essential mechanical, electrical, and patient care equipment is maintained in safe operating condition;

C0225 **CFR 485.623(b)(4)** [The CAH has housekeeping and preventive maintenance programs to ensure that-

(4) the premises are clean and orderly;

C0229 **CFR 485.623(c)(3)** [The CAH assures the safety of patients in non-medical emergencies by--

(3) providing for an emergency fuel and water supply; and.

C0240 **CFR 485.627** Organizational Structure

C0241 **CFR 485.627(a)** The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing, and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

C0264 **CFR 485.631(c)** Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist Responsibilities

C0270 **CFR 485.635** Provision of Services

C0272 **CFR 485.635(a)(2)** The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.

C0276 **CFR 485.635(a)(3)(iv)** [The policies include the following:]
(iv) rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

C0278 **CFR 485.635(a)(vi)** [The policies include the following:]
(vi) a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

C0280 **CFR 485.635(a)(4)** These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

C0282 **CFR 485.635(b)(2)** Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones);
- (ii) Hemoglobin or hematocrit;
- (iii) Blood glucose;
- (iv) Examination of stool specimens for occult blood;
- (v) Pregnancy tests; and
- (vi) Primary culturing for transmittal to a certified laboratory.

C0291 **CFR 485.635(c)(3)** The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

C0295 **CFR 485.635(d)(1)** A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available..

C0296 **CFR 485.635(d)(2)** A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

C0297 **CFR 485.635(d)(3)** All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

C0298 **CFR 485.635(d)(4)** A nursing care plan must be developed and kept current for each inpatient.

- C0300 **CFR 485.638** Clinical Records
- C0301 **CFR 485.638(a)(1)** The CAH maintains a clinical records system in accordance with written policies and procedures.
- C0302 **CFR 485.638(a)(2)** The records are legible, complete, accurately documented, readily accessible, and systematically organized.
- C0303 **CFR 485.638(a)(3)** A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.
- C0304 **CFR 485.638(a)(4)(i)** For each patient receiving health care services, the CAH maintains a record that includes, as applicable-
- (i) identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;
- C0307 **CFR 485.638(a)(4)(iv)** For each patient receiving health care services, the CAH maintains a record that includes, as applicable-]
- (iv) dated signatures of the doctor of medicine or osteopathy or other health care professional.
- C0308 **CFR 485.638(b)(1)** The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.
- C0330 **CFR 485.641** Periodic Evaluation and Quality Assurance Review
- C0331 **CFR 485.641(a)(1)** The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—
- C0332 **CFR 485.641(a)(1)(i)** [The evaluation is done at least once a year and includes review of--]
- (i) the utilization of CAH services, including at least the number of patients served and the volume of services.
- C0333 **CFR 485.641(a)(1)(ii)** [The evaluation is done at least once a year and includes review of--]
- (ii) a representative sample of both active and closed clinical records.
- C0334 **CFR 485.641(a)(1)(iii)** [The evaluation is done at least once a year and includes review of--]
- (i) the CAH's health care policies.
- C0335 **CFR 485.641(a)(2)** The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.
- C0336 **CFR 485.641(b)** The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that -
- C0337 **CFR 485.641(b)(1)** The quality assurance program requires that all patient care services and other services affecting patient health and safety are evaluated.

C0350 **CFR 485.645** A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-hospital SNF care as specified in section §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

C0361 **CFR 485.645(d)(1)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:]

(1) Resident rights (§483.10(b)(3)):

"The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;"

C0362 **CFR 485.645.(d)(1)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:]

(1) Resident rights (§483.10(b)(4)):

"The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and"

(2) Advance directive (§483.10(b)(8))

"The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time."

C0368 **CFR 485. 645(d)(1)** The resident has the right to refuse to perform services for the facility or perform services for the facility, if he or she chooses, when the facility has documented the need or desire for work in the plan of care; the plan specifies the nature of the services performed and whether the services are voluntary or paid; compensation for paid services is at or above prevailing rates; and the resident agrees to the work arrangement described in the plan of care.

C0369 **CFR 485. 645(d)(1)** The resident has the right to privacy in written communications, including the right to send and promptly receive mail that is unopened, and have access to stationery, postage, and writing implements at the resident's own expense.

C0370 **CFR 485. 645(d)(1)** The resident has the right and the facility must provide immediate access to any resident by any representative of the Secretary; subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

C0381 **CFR 485. 645(d)(3)** The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

C0385 **CFR 485.645(d)(4)** A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life. The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who--

- o Is licensed or registered, if applicable, by the State in which practicing; and
- o Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or
- o Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or
- o Is a qualified occupational therapist or occupational therapy assistant; or
- o Has completed a training course approved by the State.

C0386 **CFR 485.645(d)(5)** The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

A qualified social worker is an individual with a bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and one year of supervised social work experience in a health care setting working directly with individuals.

C0388 **CFR 485.645(d)(6)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:]

Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l), except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

Comprehensive Assessments (§483.20(b)(1))

"A facility must make a comprehensive assessment of a resident's needs ...The assessment must include at least the following:

- (i) Identification and demographic information.
- (ii) Customary routine.
- (iii) Cognitive patterns.
- (iv) Communication.
- (v) Vision.
- (vi) Mood and behavior patterns.
- (vii) Psychosocial well-being.
- (viii) Physical functioning and structural problems.
- (ix) Continence.
- (x) Disease diagnoses and health conditions.
- (xi) Dental and nutritional status.
- (xii) Skin condition.
- (xiii) Activity pursuit.
- (xiv) Medications.
- (xv) Special treatments and procedures.
- (xvi) Discharge potential.
- (xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts."

C0395 **CFR 485.645(d)(6)** The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment.

The care plan must describe the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

C0396 **CFR 485.645(d)(6)** A comprehensive care plan must be developed within 7 days after the completion of the comprehensive assessment; prepared by an interdisciplinary team that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and periodically reviewed and revised by a team of qualified persons after each assessment.

C0407 **CFR 485.645(d)(8)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:
Dental services (§483.55 of this chapter).]

" (b) Nursing facilities. The facility

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident:

- (i) Routine dental services (to the extent covered under the State plan); and
- (ii) Emergency dental services; "

C2400 **CFR 489.20(l)** [The provider agrees,] in the case of a hospital as defined in §489.24(b), to comply with §489.24.

C2406 **CFR 489.24(a)(c)** Applicability of provisions of this section.

(1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must (i) provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of §482.55 of this chapter concerning emergency services personnel and direction; and

(b) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section.

(2) Nonapplicability of provisions of this section.

Sanctions under this section for inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a

hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided for by section 1135(e)(1)(B) of the Act.

(c) Use of Dedicated Emergency Department for Nonemergency Services

If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

C2407 **CFR 489.24(d)(1-3)** (1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either-

- (i) within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.
- (ii) For transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) Exception: Application to inpatients.

- (i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual
- (ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.
- (iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment. A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

State and Federal Certification for Ambulatory Surgical Centers:

S0105 **KAR 28-34-52a** (a) The governing authority shall ensure that the facility establishes policies and procedures that support the rights of all patients.

S0145 **KAR 28-34-52(b)** The facility's policies and procedures shall establish a mechanism for responding to patient grievances and complaints.

S0150 **KAR 28-34-52(b)** Each person having a grievance or complaint pertaining to the provision of any patient services in an ambulatory surgical center may direct the grievance or complaint to the licensing department.

S0220 **KAR 28-34-52b(g)** The ambulatory surgical center shall have a written transfer agreement with a local hospital for the immediate transfer of any patient requiring medical care beyond the capability of

the ambulatory surgical center, or each physician performing surgery at the ambulatory surgical center shall have admitting privileges with a local hospital.

S0300 **KAR 28-34-54(d)** Each member of the medical staff shall submit a written application for staff membership on a form prescribed by the governing authority. After considering medical staff recommendations, the governing authority shall affirm, deny, or modify each recommendation for appointment to the medical staff.

S0320 **KAR 28-34-54(h)** The medical staff shall hold regular meetings for which records of attendance and minutes shall be kept.

S0340 **KAR 28-34-54(m)** The medical staff and the governing authority shall review the medical staff privileges at least every two years.

S0365 **KAR 28-34-55a(e)** The governing authority shall ensure that all employees are provided information related to the reporting of reportable incidents in accordance with the ambulatory surgical center's risk management plan.

S0370 **KAR 28-34-55a(f)** The governing authority shall ensure that ongoing staff education and training are provided to continually improve patient care services.

S0375 **KAR 28-34-55a(g)** The ambulatory surgical center shall maintain personnel records on each employee that shall include the job application, professional and credentialing information, health information, and annual performance evaluations

S0405 **KAR 28-34-56a(c)** The medical staff, in consultation with qualified anesthesia personnel, shall develop policies and procedures on the administration of anesthetics and drugs that produce conscious and deep sedation and on postanesthesia care . These policies and procedures shall be approved by the governing authority.

S0455 **KAR 28-34-56a(j)** All equipment for the administration of anesthetics shall be made available, cleaned with a facility-approved disinfectant and clean cloth, and maintained in good working condition.

S0550 **KAR 28-34-58a(a)(4)** The program shall include the following:
(4) orientation and ongoing education provided to all personnel on the cause, effect, transmission, and prevention of infections;

S0560 **KAR 28-34-58a(a)(6)** The program shall include the following:
(6) policies and procedures related to employee's health;

S0575 **KAR 28-34-58a(b)** Upon employment, each individual shall have a medical examination consisting of examinations appropriate to the duties of the employee, including a tuberculin skin test. Subsequent medical examinations or health assessments shall be given periodically in accordance with the facility's policies.

S0580 **KAR 28-34-58a(b)** Each ambulatory surgical center shall develop policies and procedures for the control of communicable diseases, including maintenance of immunization histories and the provision of educational materials for patient care staff. Cases of employees with tuberculin skin test conversion shall be reported to the Kansas department of health and environment.

S0590 **KAR 28-34-58a(d)(1)** Each ambulatory surgical center shall comply with the following procedures: Be kept neat, clean, and free of rubbish;

- S0595 **KAR 28-34-58a(d)(2)** Each ambulatory surgical center shall comply with the following procedures: develop written housekeeping procedures;
- S0620 **KAR 28-34-58a(g)** Staff shall make periodic checks, according to the facility's policies and procedures, throughout the premises to enforce sanitation procedures.
- S0625 **KAR 28-34-58a(h)** Sterilizing supplies and equipment. The governing authority shall establish written policies and procedures for the storage, maintenance, and distribution of supplies and equipment.
- S0650 **KAR 28-34-59a(a)** The ambulatory surgical center shall provide, either directly or through agreement, laboratory, radiology, and pharmacy services to meet the needs of the patients.
- S0655 **KAR 28-34-59a(b)** If the ambulatory surgical center provides its own clinical laboratory services, the following criteria shall be met:
 (1) The laboratory performing analytical tests within the ambulatory surgical center shall hold a valid CLIA certificate for the type and complexity of all tests performed.
- S0680 **KAR 28-34-59a(d)** Radiology services. If the ambulatory surgical center provides its own radiology services, the services shall meet the requirements specified in K.S.A. 48-1607, and amendments thereto.
- S0685 **KAR 23-34-59a(e)(1)** The ambulatory surgical center staff shall meet the following standards: Allow only trained and qualified individuals to operate radiology equipment;
- S0695 **KAR 28-34-59a(e)(3)** The ambulatory surgical center staff shall meet the following standards: ensure that all radiology and diagnostic services are provided only on the order of a physician;
- S0700 **KAR 28-34-59a(e)(4)** The ambulatory surgical center staff shall meet the following standards:
 (4) document the presence of signed and dated clinical reports of the radiological or diagnostic findings in the patient's record.
- S0720 **KAR 28-34-59a(i)** Policies and procedures. There shall be policies and procedures developed by a pharmacist, and approved by the governing authority, related to the following:
 (1) Storage of drugs;
 (2) security of drugs;
 (3) labeling and preparation of drugs;
 (4) administration of drugs; and
 (5) disposal of drugs.
- S0725 **KAR 28-34-59a(j)** All drugs and biologicals shall be ordered pursuant to a written order issued by a licensed physician.
- S0730 **KAR 28-34-59a(k)** Each adverse drug reaction shall be reported to the physician responsible for the patient and shall be documented in the patient's record.
- S0735 **KAR 28-34- 59a(l)** Drugs requiring refrigeration shall be stored in a refrigerator that is used only for drug storage.

S0740 **KAR 28-34-59a(m)** Quality assurance. There shall be a mechanism for the ongoing review and evaluation of the quality and scope of radiological, laboratory, and pharmacy services.

S0835 **KAR 28-34-61a(c)(3)** Each fire extinguisher shall be the type approved by underwriters laboratories. Extinguishers shall be inspected and tagged annually to assure that nothing has been tampered with or moved from designated areas. All extinguishers shall be functional..

(Multiple versions of "Q" tags in effect)

Q0003 **CFR 416.41** The ambulatory surgical center must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the center's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the center must assure that these services are provided in a safe and effective manner.

Q0004 **CFR 416.41(a)** The ambulatory surgical center must have an effective procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the center. This hospital must be a local, Medicare participating hospital or a local, non-participating hospital that meets the requirements for payment under section 482.2 of this chapter. The ambulatory surgical center must have a written transfer agreement with such a hospital, or all physicians performing surgery in the center must have admitting privileges at such a hospital.

Q0005 **CFR 416.42** Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ambulatory surgical center in accordance with approved policies and procedures of the center.

Q0009 **CFR 416.43** The ambulatory surgical center, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

Q0010 **CFR 416.44** The ambulatory surgical center must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

Q0012 **CFR 416.44(a)(1)** Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

Q0014 **CFR 416.44(a)(3)** The ambulatory surgical center must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

Q0018 **CFR 416.44(d)** Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ambulatory surgical center.

Q0019 **CFR 416.45** The medical staff of the ASC must be accountable to the governing body.

Q0020 **CFR 416.45(a)** Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges in accordance with recommendations from qualified medical personnel.

- Q0021 **CFR 416.45(b)** Medical staff privileges must be periodically reappraised by the ambulatory surgical center. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.
- Q0022 **CFR 416.45(c)** If the ambulatory surgical center assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.
- Q0023 **CFR 416.46** The nursing services of the ambulatory surgical center must be directed and staffed to assure that the nursing needs of all patients are met.
- Q0024 **CFR 416.46(a)** Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ambulatory surgical center.
- Q0029 **CFR 416.48** The ambulatory surgical center must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.
- Q0030 **CFR 416.48(a)** Drugs must be prepared and administered according to established policies and acceptable standards of practice.
- Q0031 **CFR 416.48(a)(1)** Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.
- Q0033 **CFR 416.48(a)(3)** Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.
- Q0034 **CFR 416.49** If the ambulatory surgical center performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter. The ASC must have procedures for obtaining radiologic services, from Medicare approved facilities, to meet the needs of patients.
- Q0040 **CFR 416.41** The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.
- Q0041 **CFR 416.41(a)** When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.
- Q0043 **CFR 416.41(c)** (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.
(2) The ASC coordinates the plan with State and local authorities, as appropriate.
(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.

- Q0061 **CFR 416.42(a)(1)** A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.
- Q0105 **CFR 416.44(c)** A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.
- Q0106 **CFR 416.44(d)** Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.
- Q0161 **CFR 416.47(a)** Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.
- Q0162 **CFR 416.47(b)** The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:
- (1) Patient identification.
 - (2) Significant medical history and results of physical examination.
 - (3) Pre-operative diagnostic studies (entered before surgery), if performed.
 - (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.
 - (5) Any allergies and abnormal drug reactions.
 - (6) Entries related to anesthesia administration.
 - (7) Documentation of properly executed informed patient consent.
 - (8) Discharge diagnosis.
- Q0180 **CFR 416.48** The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.
- Q0181 **CFR 416.48(a)** Drugs must be prepared and administered according to established policies and acceptable standards of practice.
- Q0182 **CFR 416.48(a)(1)** Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.
- Q0221 **CFR 416.50(a)(1)** The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands.
- Q0223 **CFR 416.50(a)(1)(ii)** The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.
- Q0224 **CFR 416.50(a)(2)** The ASC must comply with the following requirements:
- (i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms.
 - (ii) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.
 - (iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

Q0240 **CFR 416.51** The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

Q0241 **CFR 416.51(a)** The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

Q0242 **CFR 416.51(b)** The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

Q0243 **CFR 416.51(b)(1)** The program is - Under the direction of a designated and qualified professional who has training in infection control.

Q0245 **CFR 416.51(b)(3)** The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

State Risk Management for Acute Care, Critical Access Hospitals, and Ambulatory Surgical Centers:

R0800 **KAR 28-52-1(a)** Each medical care facility shall establish a written plan for risk management and patient care quality assessment on a facility-wide basis.

R0801 **KAR 28-52-1(b)** The plan shall be approved and reviewed annually by the facility's governing body.

R0802 **KAR 28-52-1(c)** Findings, conclusions, recommendations, actions taken, and results of actions taken shall be documented and reported through procedures established within the risk management plan.

R0805 **KAR 28-52-1(e)(2)** Plan format. Each submitted plan shall include the following:

Section II - a description of the measures used by the facility to minimize the occurrence of reportable incidents and the resulting injuries within the facility;

R0807 **KAR 28-52-1(e)(4)(A)(B)** Plan format. Each submitted plan shall include the following:

Section IV, organization - a description of the organizational elements of the plan including:

A) Name and address of the facility;

B) name and title of the facility's risk manager;

R0811 **KAR 28-52-1(e)(5)** Plan format. Each submitted plan shall include the following:
Section V – a description of the facility's resources allocated to implement the plan.

R0813 **KAR 28-52-1(f)** Plan submittal. On and after November 1, 1986, each medical care facility shall submit the plan to the department at least 60 days prior to the license renewal date. After an initial plan is approved, any amendments to the plan shall be submitted to the department.

R0819 **KSA 65-4923(a)(2)** If a health care provider, or a medical care facility agent or employee who is directly involved in the delivery of health care services, has knowledge that a health care provider

has committed a reportable incident, such health care provider, agent or employee shall report such knowledge as follows:

(2) If the reportable incident occurred within a medical care facility, the report shall be made to the chief of the medical staff, chief administrative officer or risk manager of the facility. The chief of the medical staff, chief administrative officer or risk manager shall refer the report to the appropriate executive committee, which is duly constituted pursuant to the bylaws of the facility. The committee shall investigate all such reports and take appropriate action, including recommendation of a restriction of privileges at the appropriate medical care facility. In making its investigation, the committee may also consider treatment rendered by the health care provider outside the facility.

The committee shall have the duty to report to the appropriate state licensing agency any finding by the committee that a health care provider acted below the applicable probability of causing injury to a patient, or in a manner which may be grounds for disciplinary action by the appropriate licensing agency, so that the agency may take appropriate disciplinary measures.

R0820 **KSA 65-4923(a)(3)** If the health care provider involved in the reportable incident is a medical care facility, the report shall be made to the chief of the medical staff, chief administrative officer or risk manager of the facility. The chief of the medical staff, chief administrative officer or risk manager shall refer the report to the appropriate executive committee, which is duly constituted pursuant to the bylaws of the facility. The executive committee shall investigate all such reports and take appropriate action. The committee shall have the duty to report to the department of health and environment any finding that the facility acted in a manner, which is below the applicable standard of care and which has a reasonable probability of causing injury to a patient, so that appropriate disciplinary measures may be taken.

Each review and executive committee referred to in subsection (a) shall submit to the secretary of health and environment, on a form promulgated by such agency, at least once every three months, a report summarizing the reports received pursuant to subsections (a)(2) and (a)(3) of this section. The report shall include the number of reportable incidents reported, whether an investigation was conducted and any action taken.

R0825 **KAR 28-52-2(a)** The original or complete copy of the incident report shall be sent directly to the risk manager, chief of staff, or administrator, as authorized in the facility's risk management plan.

R0826 **KAR 28-52-2(b)** The risk manager, chief of staff, or administrator shall acknowledge the receipt of each incident report in writing. This acknowledgment may be made in the following manner:

- (1) file stamping each report;
- (2) maintaining a chronological risk management reporting log;
- (3) signing or initialing each report in a consistent fashion; or
- (4) entering pertinent information into a computer database.

R0828 **KAR 28-52-3(a)** Each medical care facility shall designate one or more executive committees responsible for making and documenting standard-of-care determinations with respect to each incident report, pursuant to K.A.R. 28-52-2. The jurisdiction of each risk management committee shall be clearly delineated in the facility's risk management plan, as approved by the facility's governing body.

R0829 **KAR 28-52-3(b)** The activities of each risk management committee shall be documented in its minutes at least quarterly, and this documentation shall demonstrate that the committee is exercising overall responsibility for standard-of-care determinations delegated by the committee to individual clinical reviewers and subordinate committees.

R0830 **KAR 28-52-4(a)** Each facility shall assure that analysis of patient care incidents complies with the definition of a "reportable incident" set forth at K.S.A. 65-4921.

R0831 **KAR 28-52-4(a)(1-4)** Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:

- (1) Standards of care met;
- (2) Standards of care not met, but with no reasonable probability of causing injury;
- (3) Standards of care not met, with injury occurring or reasonably probable; or
- (4) possible grounds for disciplinary action by the appropriate licensing agency.

R0832 **KAR 28-52-4(b)** Each reported incident shall be assigned an appropriate standard of care determination under the jurisdiction of a designated risk management committee. This regulation is cited when someone reports an incident to administration or risk management and that incident is not given a standard of care by the committee. It may, also, be cited when a facility gives a standard of care, which is obviously not appropriate for the incident.

R0833 **KAR 28-52-4(b)** Separate standard of care determinations shall be made for each provider and each clinical issue reasonably presented by the facts.

This deficient practice continues to be common. Each provider involved in an incident must receive a separate standard of care determination. Many times the facilities document a standard of care determination for the incident but do not look at each involved provider. The facility fails to evaluate the impact of the provider's involvement on the patient's outcome or potential outcome. Also this regulation is cited when the findings demonstrate more than one issue, but the facility makes only one standard of care determination.

R0835 **KAR 28-52-4(c)** Each standard-of-care determination shall be dated and signed by an appropriately credentialed clinician authorized to review patient care incidents on behalf of the designated committee.

R0837 **KAR 28-52-4(c)** Standard-of-care determinations made by individual clinicians and subordinate committees shall be approved by the designated risk management committee on at least a statistical basis.