



Kansas Department of Health and Environment
Bureau of Child Care and Health Facilities
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Annual Risk Management Report for 2007

“Managing Medical Technology and Other Risk Management Challenges”

Medical technology is developing at a rapid pace. In December 2006, David Harrington, PhD, wrote an article entitled “Technology: Friend or Foe?” In this article, Mr Harrington discusses examples of what happens when entities embrace or fail to embrace cost cutting technology. Examples:

- 1) Insurance companies that do not take electronic records for drug purchases and are, therefore, unable to compete with the pharmacies that sell a 30-day supplies of generic drugs for \$4.
- 2) Urgicenters providing non-emergency care quicker and cheaper than emergency rooms and physician offices.

Mr Harrington stated, too many “look to blame technology instead of embracing it as a way to achieve cost savings.” The area of medical record technology has made a major impact on cost savings with connectivity between computer systems, voice-recognition systems, bar-coding, electronic prescriptions, etc.

President George W Bush announced in 2004 an initiative to establish the EHR (Electronic Health Record). In a March 2007 American Journal of Nursing Article, “Electronic Health Records: Useful Tools or High-Tech Headache?,” Roxanne Nelson, BSN, RN, spoke candidly of the pros and cons of the EHR. Nurses polled reported that they did not think the system decreased their workload, but felt it was more of a “help than a hindrance.” The nurses reported the EHRs did improve documentation and had the potential to improve patient care. Many believe that software and hardware vendors still feel the need to create the system for the physicians and not for the nurses.

Patrick Romero wrote in a 5/14/08 article, “Electronic Medical Records: Friend or Foe?,” that the President’s vision was that doctors would use the EHR systems with operative standards that allow sharing of lab results, images, computerized orders, prescriptions, etc with hospitals and other health facilities. Mr Romero commented that these records are not a “panacea for fixing our national medical system,” but that the systems do have much more to offer than the other modes of storing data.

Healthcare personnel are able to provide care that was only once a dream or considered science fiction. In a September 2005 Edge article, "Part 2: Bar-Coding & Implanting Humans is Here," Brenda Miller wrote about a field-tested, FDA (Food and Drug Administration) approved prototype chip with a unique verification number that can be tracked by GPS (Global Positioning System). The chip is about the size of a grain of rice and easily inserted in to humans. Many voiced concerns this technology might give potentially dangerous power to businesses and governments. Some hospitals already use bar-coding for both patients and staff. When used appropriately, errors, especially medication errors, have been reduced.

In a US News 7/8/08 article, "Slim, Flexible Stents Approved to Treat Heart Disease," Adam Vail and discussed the new generation of drug-coated stents, approved by the FDA, to be used to keep coronary blood vessels unblocked. Healthcare providers are challenged to stay abreast of this ever-changing arena impacting standards of practice and patient expectation.

Many tasks completed "manually" in the past are now managed by specialized equipment. Many tasks virtually impossible in the past are now handled with ease and split second accuracy by computers and/or other pieces of equipment.

Luckily as technology progress, the size and weight of the equipment has decreased and the accuracy and ability has increased. In the 1950s, polio victims no longer able to breathe on their own were placed in "iron lungs," with only their heads exposed. Later these were replace by likewise bulky mechanical ventilators. Thirty years ago they were the size of a small refrigerator and have continued to shrink and be perfected. MRI (Magnetic Resonance Imaging) equipment allows provider to non-invasively visualize internally like never before. At one time only available as a closed unit, open systems are now provided in many locations and greatly benefiting patients with claustrophobia.

For many years, medical facilities posted signs directing individuals to turn off their cell phones to eliminate interference with equipment in use. As digital phones replaced analog, more and more facilities not only removed the signs, but also equipped their staff with phones in place of pagers for communication and accessibility. Dr. Hazem El-Oraby quoted Barbara Christie (Purdue School of Engineering and Technology) in a 7/15/08 article, "RFID [Radio-Frequency Identification device] vs Medical Devices; Friend or Foe," that a Dutch study reflecting interference did not test RFID devices on medical equipment in typical settings. Per Ms Christie, "If I swallow my cell phone, I may have some type of hazardous interaction, but that is not an appropriate or typical use of a cell phone." Per Ms Christie's study, no interference occurred during 1600 tests conducted in a patient room, using two common RFID antennas in far fields and as close as one foot from medical equipment (pumps, non-invasive blood pressure monitors, sequential compression devices, electrocardiogram monitors, and pulse oximetry monitors).

Just as providers no longer fear interference from current cell phones and other RFID, they must continue to be alert to the possibility of security breaches with cell phone use, in addition to those concerns related to electronic records. In an undated brochure by the US Department of Homeland Security, "Wireless Technology Friend or Foe?," "rogue" wireless access and countermeasures were discussed. Included in the information were the following warnings:

- 1) "Bluetooth capability can also be remotely enabled without the user's knowledge."
- 2) USB Memory Sticks/Flash drives are often lost or left in the office, making them an easy target. "This poses a security officer's worst nightmare, because in most cases, the owner

A facility working to meet the challenge to provide “cutting edge” care is faced not only with securing the necessary technology, protecting the data, and training staff, but also, where to put the equipment. Patient rooms built more than 10 years ago are frequently busting at the seams to contain the equipment necessary in the provision of care to meet a patient’s needs. At times, it is difficult to get the equipment and the patient in the room. Then staff and family struggle through a maze of equipment, lines, and cords.

Additionally, staff are responsible for not only the patient, but also the equipment. At times, the equipment can be very demanding. Alarms sound, error messages flash, equipment fails, server’s crash. Some staff have become so dependent on the equipment to give them vital patient information, that they are lost when the equipment does not work properly. More than one healthcare worker confessed to initiating a “Code Blue” because the monitor indicated a cardiac arrest, only to have the bewildered patient interrupt the mobilizing staff by asking what was happening. At that time, staff discovered that cardiac monitor leads were dislodged, cable disconnected, dead batteries, and a sleuth of other reasons leading to the false assumption. Staff allowed the equipment to replace their skills and expertise to assess the patient.

Then there is the issue of staff turning off warning alarms because they are “bothersome.” Each year, adverse event reports include this inappropriate action by staff. Some of these incidents ended in severe injury or death of the patient. Initially, the incidents are often reported as “equipment failure.” Once the equipment is determined to be functioning appropriately, staff frequently confess to turning off the alarms.

Patients occasionally report that the only time staff touched them or spoke to them was purely in the course of performing a task. Much has changed since the time when a bedtime backrub was routine. Healthcare has come a long way in meeting the physical needs of the patient. With the shorten stays in healthcare facilities and the increased demands on staff by the very technology that allows them to do more with less, psychological needs of the patient and their families has unfortunately become less of a priority, in more and more instances. Physical needs are easier to identify and treat. Psychological needs are more difficult, but have not lost their importance in the overall well-being of the patient. Seeing the need, several facilities now employ patient advocates - paid and volunteer – to help meet these very important needs once met by nursing staff.

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.

Even with the best of the best, things do not always go as planned and hoped. Under risk management, providers are given an opportunity to candidly evaluate the event and make corrective action as warranted.

An area of concern is the facility’s failure to investigate “near misses” through risk management. Although the error was caught, something happened or did not happen that should have and a near miss, or close call, occurred. A primary purpose for evaluating near misses and other

adverse events is to develop systems to prevent or reduce the potential for a repeat of events. If left unchecked, history **will** repeat itself.

Risk management programs should be proactive. They should actively identify areas of concern and potential areas of concern, and changing/adapting to meet the ever-changing challenges in the provision of healthcare. A facility can never let their guard down. Errors continue to be made.

In a Washington Post 7/22/08 article, "When It's Surgery, Don't Get It Wrong," Tracy Grant related a recent "near miss" experience involving one of her sons and research by John R Clarke, clinical director of the Pennsylvania Patient Safety Reporting System. According to Dr Clarke, surgical mistakes involving the wrong side of the patient occur three times a day in the US. Dr Clarke's study compared the wrong side near misses and actual wrong site surgeries. In this study, Dr Clarke found the number one action that prevented the errors was the patient or family surrogate "speaking up."

A 7/18/08 Institute for Safe Medication Practices article, "Heparin Errors Continue Despite Prior, High-Profile, Fatal Events," discusses multiple failures leading to heparin errors. The July 2008 errors in a Texas hospital neonatal intensive were related to a pharmacy mixing process. At least 14 infants received as much as 100 times more heparin than intended. Astute neonatal nurses noted the babies' abnormal laboratory values and uncovered the errors.

One solution considered by the involved hospital is barcode technology during the mixing process. "It's frustrating and tragic that heparin errors continue to happen and harm neonates. At this point, every hospital in the nation should be conducting a failure mode and effects analysis regarding the use of heparin in neonates, both in flush solutions and when added to infusate." We also need to think ahead and consider whether our solutions today will still be effective in tomorrow's healthcare system."

On 7/11/08, Joe Tye, America's Values Coach, wrote in his article, "Never Fear Trying, Never Quit Caring," excerpts from his book, Never Fear, Never Quit. Mr Tye quoted Confucius as saying that "to see what is right and not to do it is cowardice." Also the reverse is true. To do what you know is right, even when it is difficult or unpopular, is courage. Caring is the root of courage and gives a person the courage "to never fear trying," and do what is right. 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 carry a lot of wisdom for managing risk.

In 2005 and 2006, the Kansas Risk Management Specialist participated with other states and the AHRQ and the Veterans Administration's NCPS in Patient Safety training and continues to be in contact with AHRQ. In September 2007, the Kansas Risk Management Specialist joined representatives from 12 other states in The Pennsylvania Patient Safety Learning Exchange: Helping States Improve and Integrate Patient Safety Initiatives sponsored by NASHP (National Academy for State Health Policy).

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 are under review by KDHE 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 live in a safe environment and be treated justly.

Members from KARQM and KHA 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. 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 25 % of the hospitals completed this part of the quarterly report during 2007.

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 the process is in place that would prevent anyone from operating on the wrong limb or the wrong eye. Pre-operative surgical site designation and “time out” has become the standard. Yet in Kansas, we continue to have wrong site surgeries reported.

It has been more than ten 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. 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 are 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.” 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.

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.

Brief History of Kansas Risk Management

This report represents the nineteenth 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. 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.

“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.

Ambulatory Surgical Centers

KDHE implemented a revised certification, licensure and risk management survey process for ASCs in the spring of 2001 using the revised state regulations approved in April 2001. In FY 2008, 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 additional surveys to insure that no more than seven years elapses between surveys of any one ASC provider, and
- 3) ensure that all ASC providers are surveyed at least every six years, on average.

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, 2007, there were sixty-five 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. In 2006, federal certification frequency requirements were lengthened to a resurvey every six years. Since many of the regulations are similar, the federal certification resurvey and licensure/risk management processes were combined to meet the increased workload. In FY 2008, CMS mandates 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.

Kansas continues to lead the states in the number of CAHs. As of December 31, 2008, 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 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, along with the State Survey Manager, 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 2007, 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 one to three days. When deficiencies are cited, the facility may receive a revisit within six months. A survey revisit is usually accomplished in four to eight hours.

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 2008

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

for

Risk Management/Licensure and Certification

Survey Process

Glossary of Terms

Tables

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 | Kansas Administrative Regulations |
| CDC | Centers for Disease Control |
| CFR | Code of Federal Regulations |
| CMS | Centers for Medicare and Medicaid Services |
| 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 |
| 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) Tags |

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 2005 and are presented in the following tables. In addition, two columns have been added in 2001 to separate the number of reportable incidents into the two categories of SOC III which is standard of care not met, with injury occurring or reasonably probable and SOC IV which is possible grounds for disciplinary action by the appropriate licensing agency.

Table 1*
Comparison of Reportable Incidents By Year and By Licensing Agency 1992 – 2007

| Year | Total # of Reportable SOCs | SOC III | SOC IV | KSBHA | KSBN | KDHE | KSBP | Other |
|------|----------------------------|---------|--------|-----------|------------|------------|----------|----------|
| 1992 | 664 | | | 101 (15%) | 260 (39%) | 132 (20%) | N/A | 171(26%) |
| 1993 | 571 | | | 80 (14%) | 304(53%) | 123 (22%) | N/A | 64 (11%) |
| 1994 | 569 | | | 64 (11%) | 273 (48%) | 134 (24%) | N/A | 89 (16%) |
| 1995 | 530 | | | 103(19%) | 230 (43%) | 130(25%) | N/A | 67 (13%) |
| 1996 | 512 | | | 69 (13%) | 268(52%) | 143(28%) | N/A | 32 (7%) |
| 1997 | 488 | | | 66 (14%) | 257 (52%) | 140(29%) | N/A | 25 (5%) |
| 1998 | 361 | | | 46 (13%) | 198(55%) | 84 (23%) | 7 (2%) | 27 (7%) |
| 1999 | 441 | | | 65 (15%) | 186 (42%) | 151(34%) | 12 (3%) | 27 (6%) |
| 2000 | 571 | | | 72 (13%) | 285(50%) | 191 (34%) | 3 (.05%) | 20 (4%) |
| 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%) |

***Table 1** above depicts the number of incidents reported to licensing agencies for the years 1992-2003. The 1998 figure is the lowest number in the ten reporting years and represents a significant decrease from all of the other years. There was a decrease in the number of issues reported to risk management and a decrease in the number of reportable incidents to all licensing agencies in 2nd quarter 1998. It did slowly increase in 3rd and 4th quarter, 1998. There was a decrease in 1999 followed by a sharp increase in 2000. Another decrease in 2001 followed by an increase in 2002 and 2003.

**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.

Table 2

Comparison of Total Number of **Reportable Incidents** Generated By Facility Size and Licensing Agency
1996-2007

| Facility Size | Year | KSBHA | KSBN | KDHE | Pharmacy | Other |
|---------------|------|-------------|-------------|-------------|-------------|-------------|
| 1-25 beds | 2007 | 16(10.5%) | 79(51.9%) | 48(31.6%) | 5(3.3%) | 4(2.7%) |
| | 2006 | 21 or 12.1% | 61 or 35.3% | 55 or 31.8% | 15 or 8.7% | 21 or 12.1% |
| | 2005 | 16 or 9.5% | 59 or 34.9% | 89 or 52.4% | 2 or 1.2% | 3 or 1.8% |
| | 2004 | 18 or 14% | 40 or 31% | 59 or 46% | 1 or 1% | 10 or 8 % |
| | 2003 | 19 (13.6%) | 79 (56.5 %) | 32 (22.8%) | 8 (5.7 %) | 1 (1.4%) |
| | 2002 | 6 or 7% | 29 or 32% | 53 or 38% | 1 of 1% | 3 or 3 % |
| | 2001 | 4 or 5% | 36 or 45% | 34 or 42% | 1 or 1% | 6 or 7% |
| | 2000 | 16 or 18% | 47 or 54% | 17 or 20% | 1 or 1% | 6 or 7% |
| | 1999 | 4 or 6% | 32 or 46% | 24 or 34% | 3 or 4% | 7 or 10% |
| | 1998 | 5 or 11% | 30 or 67% | 7 or 15% | 0 | 3 or 7% |
| | 1997 | 4 or 8 % | 29 or 56% | 17 or 33% | 0 | 2 or 3% |
| | 1996 | 4 or 9% | 24 or 56% | 13 or 30% | 2 or 5% | 0 |
| 25-50 beds | 2007 | 15(38.5%) | 15(38.5%) | 9(2.23%) | 0 | 0 |
| | 2006 | 2 or 6.5% | 16 or 51.6% | 1 or 3.2 % | 3 or 9.7% | 9 or 29% |
| | 2005 | 1 or 3.3% | 20 or 66.7% | 8 or 26.7% | 0 | 1 or 3.3% |
| | 2004 | 4 or 6% | 29 or 40% | 39 or 54% | 0 | 0 |
| | 2003 | 23 or 23.9% | 35 or 38% | 28 or 34.4% | 5 or 5.4% | 1 or 1% |
| | 2002 | 9 or 13% | 38 or 53% | 22 or 31% | 3 or 4% | 0 |
| | 2001 | 17 or 24% | 36 or 50% | 20 or 28% | 3 or 4% | 3 or 4% |
| | 2000 | 11 or 12% | 39 or 42% | 35 or 38% | 0 | 7 or 8% |
| | 1999 | 14 or 17% | 45 or 55% | 19 or 23% | 1 or 1% | 3 or 4% |
| | 1998 | 13 or 15% | 41 or 48% | 27 or 31% | 0 | 5 or 6% |
| | 1997 | 24 or 24% | 42 or 42% | 24 or 24% | 3 or 3% | 6 or 6% |
| | 1996 | 16 or 17% | 43 or 46% | 27 or 29% | 0 | 7 or 8% |
| 51-100 beds | 2007 | 5(10.2%) | 23(51%) | 12(24.5%) | 1(2%) | 5(10.2%) |
| | 2006 | 15 or 22.4% | 44 or 65.7% | 0 | 1 or 1.5% | 7 or 10.4% |
| | 2005 | 3 or 3.9% | 41 or 53.2% | 13 or 16.9% | 16 or 20.8% | 4 or 5.2% |
| | 2004 | 5 or 12% | 24 or 56% | 7 or 16% | 2 or 5% | 5 or 12% |
| | 2003 | 4 or 11% | 17 or 41.5% | 15 or 36.6% | 0 | 2 or 4.9% |

| Facility Size | Year | KSBHA | KSBN | KDHE | Pharmacy | Other |
|---------------|-----------|-------------|--------------|--------------|-----------|-------------|
| | 2002 | 6 or 9% | 25 or 36% | 34 or 49% | 2 or 3% | 2 or 3% |
| | 2001 | 4 or 11% | 21 or 54% | 9 or 24% | 0 | 4 or 11% |
| | 2000 | 22 or 26% | 39 or 45% | 25 or 29% | 0 | 1 or 1% |
| | 1999 | 15 or 23% | 22 or 34% | 21 or 33% | 0 | 6 or 10% |
| | 1998 | 12 or 20% | 34 or 57% | 7 or 12% | 2 or 3% | 5 or 8% |
| | 1997 | 7 or 8% | 54 or 61% | 22 or 25% | 1 or 1% | 5 or 5% |
| | 1996 | 13 or 16% | 34 or 43% | 29 or 36% | 3 or 4% | 1 or 15 |
| 101-200 beds | 2007 | 15(25.9%) | 29(50%) | 4(6/9%) | 9(15.5%) | 1(1.7%) |
| | 2006 | 13 or 36.1% | 18 or 50% | 1 or 2.8% | 0 | 4 or 11.1% |
| | 2005 | 4 or 9.3% | 35 or 81.4% | 2 or 4.6 % | 0 | 2 or 4.6% |
| | 2004 | 18 or 17% | 65 or 65% | 21 or 19% | 3 or 3% | 1 or 1% |
| | 2003 | 0 | 10 or 52.6% | 9 or 47.4% | 0 | 0 |
| | 2002 | 9 or 17% | 36 or 67% | 8 or 15% | 1 or 2% | 0 |
| | 2001 | 6 or 11% | 38 or 69% | 10 or 18% | 0 | 1 or 2% |
| | 2000 | 5 or 9% | 38 or 67% | 13 or 23% | 0 | 0 |
| | 1999 | 10 or 15% | 34 or 51% | 7 or 10% | 7 or 10% | 9 or 13% |
| | 1998 | 6 or 9% | 51 or 74% | 5 or 7% | 5 or 7% | 2 or 3% |
| | 1997 | 16 or 20% | 50 or 61% | 11 or 13% | 2 or 2% | 2 or 4% |
| | 1996 | 10 or 11% | 57 or 60% | 15 or 16% | 1 or 1% | 12 or 12% |
| | 201+ beds | 2007 | 16(7%) | 101(41%) | 122(50%) | 3(1%) |
| 2006 | | 13 or 6.5% | 96 or 47.8% | 5 or 2.5% | 6 or 3% | 81 or 40.3% |
| 2005 | | 18 or 5.3% | 181 or 57.8% | 104 or 33.2% | 4 or 1.3% | 6 or 1.9% |
| 2004 | | 14 or 10% | 2 or 19% | 91 or 65% | 4 or 3% | 3 or 2% |
| 2003 | | 19 or 48.7% | 1 or 2.5 % | 17 or 41.5% | 1 or 2.6% | 1 or 2.6% |
| 2002 | | 13 or 8% | 87 or 50% | 59 or 34% | 8 or 5% | 6 or 3 % |
| 2001 | | 17 or 9% | 85 or 45% | 76 or 40% | 10 or 5% | 3 or 1% |
| 2000 | | 16 or 7% | 122 or 50% | 101 or 41% | 2 or .08% | 3 or 1% |
| 1999 | | 22 or 14% | 53 or 34% | 79 or 50% | 1 or 1% | 2 or 1% |
| 1998 | | 10 or 10% | 42 or 41% | 38 or 37% | 0 | 12 or 12% |
| 1997 | | 15 or 9% | 80 or 49% | 66 or 40% | 2 or 1% | 3 or 1% |
| 1996 | | 23 or 12% | 110 or 57% | 57 or 29% | 1 or 1% | 3 or 1 |

| Facility Size | Year | KSBHA | KSBN | KDHE | Pharmacy | Other |
|---------------|------|----------|------------|------------|----------|----------|
| ASCs | 2007 | 3(43%) | 0 | 3(43%) | 0 | 1(14%) |
| | 2006 | 4 or 20% | 8 or 40% | 0 | 1 or 5% | 7 or 35% |
| | 2005 | 2 or 25% | 3 or 37.5% | 3 or 37.5% | 0 | 0 |
| | 2004 | 2 or 29% | 3 or 43% | 2 or 28% | 0 | 0 |
| | 2003 | 0 | 0 | 0 | 0 | 0 |
| | 2002 | 1 or 8% | 0 | 3 or 23% | 0 | 9 or 69% |
| | 2001 | 0 | 0 | 0 | 0 | 0 |
| | 2000 | 2 or 40% | 0 | 0 | 0 | 3 or 60% |
| | 1999 | 0 | 0 | 1 or 100% | 0 | 0 |
| | 1998 | 0 | 0 | 0 | 0 | 0 |
| | 1997 | 0 | 2 or 100% | 0 | 0 | 0 |
| | 1996 | 3 or 42% | 0 | 2 or 29% | 0 | 2 or 29% |

***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 2000 – 2007

| Facilities by Bed Size/ Category | Number of Facilities in Size Category 2007 | Avg # of SOC's/ Total # of Reportable SOC's Reviewed 2000 | Avg # of SOC's/ Total # of Reportable SOC's Reviewed 2001 | Avg # of SOC's/ Total # of Reportable SOC's Reviewed 2003 | Avg # of SOC's/ Total # of Reportable SOC's Reviewed 2004 | Avg # of SOC's/ Total # of Reportable SOC's Reviewed 2005 | Avg # of SOC's/ Total # of Reportable SOC's Reviewed 2006 | Avg # of SOC's/ Total # of Reportable SOC's Reviewed 2007 |
|----------------------------------|--|---|---|---|---|---|---|---|
| 1 - 25 | 93 | 218/97 | 213/97 | 238/140 | 264.3/127 | 296.9/169 | 351/176 | 408.4/152 |
| 26 - 50 | 13 | 373/102 | 362/71 | 385/75 | 413.8/51 | 492.8/30 | 501.8/31 | 544.2/39 |
| 51 - 100 | 25 | 591/86 | 485/38 | 568/88 | 606/45 | 555.8/77 | 596.8/67 | 524.9/49 |
| 101 - 200 | 13 | 906/7 | 780/55 | 1097/60 | 1009/108 | 703.4/43 | 1049/36 | 1221.5/58 |
| 200 + | 13 | 2093/242 | 2057/191 | 2803/201 | 208.9/179 | 2873/313 | 3044/201 | 2701/243 |
| ASCs | 65 | 24/5 | 28.5/0 | 33.7/0 | 29.8/9 | 39.6/8 | 37/20 | 34.8/7 |
| Totals | 222 | /571 | /436 | 436.8/564 | 427/519 | 469.5/640 | 506.1/531 | 501.9/548 |

***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.

APPENDIX A

Total of Survey Codes Cited During 53 **Acute Care Hospital** Licensure/Certification Surveys 2007

| SURVEY CODES | # OF CITES | SURVEY CODES | # OF CITES | SURVEY CODES | # OF CITES | SURVEY CODES | # OF CITES | SURVEY CODES | # OF CITES |
|--------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|
| H0004 | 1 | A0054 | 1 | A0183 | 1 | A0303 | 1 | A0459 | 1 |
| H0016 | 1 | A0056 | 2 | A0186 | 1 | A0318 | 1 | A0460 | 1 |
| H0032 | 1 | A0057 | 1 | A0188 | 1 | A0331 | 1 | A0466 | 1 |
| H0042 | 4 | A0058 | 3 | A0199 | 4 | A0339 | 2 | A0468 | 1 |
| H0063 | 2 | A0059 | 1 | A0200 | 1 | A0340 | 3 | A0500 | 1 |
| H0071 | 1 | A0060 | 1 | A0201 | 1 | A0351 | 1 | A0501 | 1 |
| H0074 | 1 | A0066 | 2 | A0202 | 1 | A0353 | 1 | A0505 | 1 |
| H0113 | 1 | A0068 | 1 | A0204 | 5 | A0358 | 1 | A0629 | 1 |
| H0114 | 2 | A0069 | 1 | A0205 | 7 | A0385 | 1 | A0632 | 1 |
| | | A0083 | 1 | A0206 | 1 | A0390 | 1 | A0700 | 1 |
| A0005 | 1 | A0095 | 1 | A0209 | 1 | A0392 | 3 | A0724 | 3 |
| A0006 | 3 | A0115 | 1 | A0210 | 2 | A0395 | 3 | A0749 | 1 |
| A0009 | 1 | A0117 | 1 | A0214 | 1 | A0396 | 4 | A1011 | 1 |
| A0021 | 1 | A0119 | 1 | A0223 | 2 | A0400 | 11 | A1508 | 1 |
| A0028 | 3 | A0123 | 1 | A0227 | 4 | A0402 | 1 | A1510 | 1 |
| A0029 | 1 | A0130 | 1 | A0229 | 4 | A0404 | 1 | A1513 | 1 |
| A0038 | 1 | A0131 | 1 | A0230 | 6 | A0405 | 2 | A1537 | 1 |
| A0040 | 2 | A0144 | 1 | A0251 | 1 | A0406 | 13 | A2400 | 1 |
| A0041 | 1 | A0145 | 1 | A0254 | 1 | A0431 | 1 | A2402 | 1 |
| A0042 | 1 | A0147 | 2 | A0255 | 3 | A0438 | 1 | A2404 | 1 |
| A0044 | 1 | A0148 | 1 | A0256 | 1 | A0441 | 1 | A2405 | 1 |
| A0045 | 1 | A0150 | 1 | A0275 | 1 | A0442 | 2 | A2406 | 1 |
| A0046 | 3 | A0156 | 2 | A0276 | 1 | A0451 | 2 | | |
| A0048 | 2 | A0165 | 1 | A0295 | 1 | A0452 | 4 | | |
| A0051 | 2 | A0168 | 1 | A0297 | 1 | A0454 | 1 | | |
| A0052 | 2 | A0171 | 1 | A0298 | 2 | A0455 | 1 | | |
| A0053 | 1 | A0174 | 1 | A0300 | 1 | A0456 | 1 | | |

APPENDIX B

Total of Survey Codes Cited During 25 Critical Access Hospital Certification Surveys 2007

| SURVEY CODES | # of CITES | SURVEY CODES | # of CITES | SURVEY CODES | # of CITES | SURVEY CODES | # of CITES |
|--------------|------------|--------------|------------|--------------|------------|--------------|------------|
| C0153 | 1 | C0276 | 4 | C0333 | 1 | C0385 | 1 |
| C0154 | 1 | C0279 | 1 | C0337 | 1 | C0388 | 1 |
| C0204 | 1 | C0280 | 1 | C0361 | 2 | C0389 | 1 |
| C0205 | 1 | C0283 | 1 | C0364 | 1 | C0395 | 2 |
| C0207 | 3 | C0291 | 1 | C0366 | 1 | C0396 | 1 |
| C0222 | 2 | C0296 | 3 | C0368 | 3 | | |
| C0223 | 1 | C0297 | 2 | C0369 | 3 | | |
| C0224 | 1 | C0298 | 2 | C0370 | 2 | | |
| C0225 | 3 | C0300 | 1 | C0371 | 2 | | |
| C0226 | 2 | C0301 | 1 | C0372 | 3 | | |
| C0240 | 1 | C0302 | 1 | C0374 | 1 | | |
| C0241 | 2 | C0304 | 2 | C0377 | 1 | | |
| C0256 | 1 | C0307 | 16 | C0378 | 1 | | |
| C0257 | 1 | C0308 | 21 | C0379 | 2 | | |
| C0271 | 2 | C0321 | 1 | C0381 | 2 | | |

APPENDIX C

Total of Survey Codes Cited During 27 **Ambulatory Surgical Center** Licensure and Certification Surveys 2007

| SURVEY CODES | NUMBER OF FACILITIES CITED | SURVEY CODES | NUMBER OF FACILITIES CITED | SURVEY CODES | NUMBER OF FACILITIES CITED |
|--------------|----------------------------|--------------|----------------------------|--------------|----------------------------|
| Q0009 | 1 | S0145 | 1 | S0570 | 2 |
| Q0021 | 2 | S0150 | 1 | S0575 | 2 |
| | | S0375 | 1 | | |
| S0140 | 1 | S0530 | 1 | | |

APPENDIX D

Total of Survey Codes cited During 32 Hospital, CAH and ASC **Risk Management** Surveys 2007

| SURVEY CODES | NUMBER OF FACILITIES CITED | SURVEY CODES | NUMBER OF FACILITIES CITED | SURVEY CODES | NUMBER OF FACILITIES CITED |
|--------------|----------------------------|--------------|----------------------------|--------------|----------------------------|
| R0801 | 2 | R0826 | 1 | R0836 | 1 |
| R0802 | 2 | R0828 | 1 | | |
| R0810 | 1 | R0829 | 1 | | |
| R0811 | 1 | R0832 | 5 | | |
| R0815 | 1 | R0833 | 4 | | |
| R0819 | 3 | R0834 | 1 | | |
| R0820 | 2 | R0835 | 2 | | |

APPENDIX E

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 53 **Hospital** Certification & Licensure 2007

| Survey Code | Number of Times Survey Code Cited | Percentage of Facilities Cited |
|--|-----------------------------------|--------------------------------|
| A0406 – Medical Screening Exam | 12 | 23% |
| A0400 – Compliance with CFR 489.24 | 11 | 21% |
| A0318 – Maintenance of Physical Plant | 7 | 13% |
| A0205 – Nursing Care Plan | 6 | 11% |
| A0230 – Authentication of Entries in Records | 6 | 11% |

APPENDIX F

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 25 **CAH Hospital** Certification Surveys 2007

| Survey Code | Number of Times Survey Code Cited | Percentage of Facilities Cited |
|------------------------------------|-----------------------------------|--------------------------------|
| C0307 - Record System | 16 | 64% |
| C0302 – Record System | 5 | 20% |
| C0276 - Policies – Drug Management | 4 | 16% |

APPENDIX G

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 29 **Hospital & CAH** Risk Management Surveys 2007

| Survey Code | Number of Times Survey Code Cited | Percentage of Facilities Cited |
|---|-----------------------------------|--------------------------------|
| R0832 – Appropriate SOC determination | 5 | 17% |
| R0833 – Separate SOC per provider and clinical issue | 4 | 14% |
| R0829 – Documentation of risk management committee activities | 3 | 10% |

APPENDIX H

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During **ASC** Surveys – 25 Certification & Licensure and 3 Risk Management Surveys 2007

| Survey Code | Number of Times Survey Code Cited | Percentage of Facilities Cited |
|---------------------------|-----------------------------------|--------------------------------|
| Q0021 – Reappraisals | 2 | 8% |
| S0560 – Infection Control | 2 | 8% |
| S0572 – Infection Control | 2 | 8% |

APPENDIX I

2007 Cited Survey Codes

State Licensure and Federal Certification Acute Care Hospital:

H0004 **KAR 28-34-3a(f)** The hospital shall develop an internal disaster and fire plan incorporating evacuation procedures. This plan shall be made available to all personnel and shall be posted throughout the building.

H0016 **KAR 28-34-5a(c)** At a minimum the governing body shall: (1) Provide adequate physical resources and personnel for appropriate patient care; (2) participate in planning to define and help meet the health needs of the community;

H0032 **KAR 28-34-7(f)** There shall be at least one registered nurse on duty in the hospital at all times.

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.

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.

H0071 **KAR 28-34-16a(b)(1)** Organized emergency services. In hospitals with organized emergency services, the following shall apply: (1) Emergency services shall be available 24 hours a day, and medical staff coverage shall be adequate so that the patient will be seen within a period of time which is reasonable relative to the severity of the patient's illness or injury.

H0072 **KAR 28-34-16a(b)(3)** The emergency service, regardless of its scope, shall be organized and integrated with other departments of the hospital.

H0113 **KAR 28-34-18a(c)(2)** Each delivery room shall have access to the following:

- (A) Equipment appropriate for maternal and newborn resuscitation, including suction, airways, endotracheal tubes, and ambu bags;
- (B) Equipment for administration of inhalation and regional anesthetics;
- (C) A functioning source of emergency electrical power;
- (D) An emergency call or intercommunication system;
- (E) Oxygen and suction equipment which can be accurately regulated;
- (F) A fetal monitor;
- (G) Supplies and instruments for emergency Cesarean section;
- (H) A scrub sink with foot, knee, or elbow control;
- (I) Prophylactic solution approved by the licensing agency for instillation into eyes of newborn pursuant to K.S.A. 64-153 and K.A.R. 28-4-73 and any amendments thereto;
- (J) A method for identification of the newborn and mother;

- (K) A movable, heated bassinet, a bassinet with a radian warmer, or a transport isolette for the newborn while in the delivery room and during transport from the delivery room; and
- (L) A sink with foot, knee, or elbow control.

H0114 **KAR 28-34-18a(c)(3)** Each normal or neonatal intensive care nursery shall have access to the following:

- (A) A bassinet or isolette for the exclusive use of each infant and for storage or individualized equipment and supplies;
- (B) Oxygen, oxygen analyzer, and suction equipment which can be accurately regulated;
- (C) Phototherapy light
- (D) Intravenous infusion solutions and equipment. A pump shall also be available;
- (E) ; Sink with foot, knee, or elbow control; and
- (F) Newborn resuscitation equipment.

(Multiple versions of "A" tags in effect)

A0005 **CFR 482.11(c)** The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

A0006 **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.

A0009 **CFR 482.12** The governing body must appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

A0021 **CFR 482.12(c)(4)** A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization; and is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is defined by the medical staff; permitted by State law; and limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

A0028 **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.

A0029 **CFR 482.12(e)(2)** The hospital must maintain a list of all contracted services, including the scope and nature of the services provided

A0038 **CFR 482.13** A hospital must protect and promote the rights of each patient.

A0040 **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.

A0041 **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.

A0042 **CFR 482.13(a)(2)** 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.

- A0044 **CFR 482.13(a)(i)** The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.
- A0045 **CFR 482.13(a)(ii)** The grievance process must specify time frames for review of the grievance and the provision of a response.
- A0046 **CFR 482.13(a)(iii)** 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.
- A0048 **CFR 482.13(b)(1)** The patient has the right to participate in the development and implementation of his or her plan of care.
- A0051 **CFR 482.13(b)(2)** The patient's rights include being involved in care planning and treatment.
- A0052 **CFR 482.13(b)(2)** The patient's rights include being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.
- A0053 **CFR 482.13(b)(3)** The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).
- A0054 **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.
- A0056 **CFR 482.13(c)(1)** The patient has the right to personal privacy.
- A0057 **CFR 482.13(c)(2)** The patient has the right to receive care in a safe setting.
- A0058 **CFR 482.13(c)(3)** The patient has the right to be free from all forms of abuse or harassment.
- A0059 **CFR 482.13(d)** Confidentiality of Patient Records Standard.
- A0060 **CFR 482.13(d)** The patient has the right to the confidentiality of his or her clinical records.
- A0066 **CFR 482.13(e)(3)(ii)** The use of a restraint must be in accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint.
- A0068 **CFR 482.13(e)(3)(ii)(B)** The order for restraint must be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician.
- A0069 **CFR 482.13(e)(3)(iii)** The use of restraint must be in accordance with a written modification to the patient's plan of care.
- A0083 **CFR 482.13(f)(3)(ii)(A)** Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9.

A0095 **CFR 482.13(f)(7)** The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

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.

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.

A0131 **CFR 482.13(b)(2)** The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.

The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

A0144 **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 identify and reduce medical errors.

A0145 **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.

A0147 **CFR 482.21(b)(1)** The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from the hospital's Quality Improvement Organization (QIO).

A0148 **CFR 482.21(b)(2)(ii)** The hospital must use the data collected to monitor the effectiveness and safety of service and quality of care.

A0150 **CFR 482.21(b)(3)** The frequency and detail of data collection must be specified by the hospital's governing body.

A0156 **CFR 482.21(c)(2)** Performance improvement activities must implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

- A0165 **CFR 482.21(d)(3)** The hospital must document the measurable progress achieved on performance improvement projects.
- A0168 **CFR 482.21(e)(1)** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that an ongoing program for quality improvement is defined, implemented, and maintained.
- A0171 **CFR 482.21(e)(2)** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that the hospital-wide quality assessment and performance improvement efforts address priorities for improved patient safety and that all improvement actions are evaluated.
- A0174 **CFR 482.21(d)(4)** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that adequate resources are allocated for reducing risk to patients.
- A0183 **CFR 482. 22(a)(4)** The medical staff must periodically conduct appraisals of its members.
- A0186 **CFR 482.22(c)** The medical staff must periodically conduct appraisals of its members.
- A0188 **CFR 482.22(c)(2)** The bylaws must include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)
- A0199 **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.
- A0200 **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.
- A0201 **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.
- A0202 **CFR 482.23(b)(1)** The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.
- A0204 **CFR 482.23(b)(3)** A registered nurse must supervise and evaluate the nursing care for each patient.
- A0205 **CFR 482.23(b)(4)** The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

- A0206 **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.
- A0209 **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.
- A0210 **CFR 482.23(c)(2)** All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under §482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications.
- A0214 **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.
- A0223 **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.
- A0227 **CFR 482.24(b)(3)** The hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.
- A0229 **CFR 482.24(c)** 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.
- A0230 **CFR 482.24(c)(1)** All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.
- A0251 **CFR 482.25(a)(3)** Current and accurate records must be kept of the receipt and distribution of all scheduled drugs.
- A0254 **CFR 482.25(b)(2)** Drugs and biologicals must be kept in a locked storage area.
- A0255 **CFR 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.
- A0256 **CFR 482.25(b)(4)** When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law
- A0275 **CFR 482.26(c)(1)** A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiological tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

- A0276 **CFR 482.26(c)(3)** Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
- A0295 **CFR 482.28** The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.
- A0297 **CFR 482.28(a)(1)** The hospital must have a full-time employee who serves as director of the food and dietetic services; is responsible for daily management of the dietary services; and is qualified by experience or training.
- A0298 **CFR 482.28(a)(2)** There must be a qualified dietitian, full-time, part-time, or on a consultant basis.
- A0300 **CFR 482.28(b)** Menus must meet the needs of the patients.
- A0303 **CFR 482.23(b)(3)** A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.
- A0318 **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.
- A0331 **CFR 482.41(c)(2)** Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
- A0339 **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.
- A0340 **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.
- A0351 **CFR 482.43(b)(1)** The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.
- A0353 **CFR 482.43(b)(3)** The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.
- A0358 **CFR 482.43(c)(1)** A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.
- A0385 **CFR 482.51(a)** The organization of the surgical services must be appropriate to the scope of the services offered.
- A0390 **CFR 482.51(b)** Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

A0392 **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.

A0395 **CFR 482.51(b)(5)** The operating room register must be complete and up to date.

A0396 **CFR 482.51(b)(6)** An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

A0400 **CFR 489.20(l)** The provider agrees, in the case of a hospital as defined in §489.24(b), to comply with §489.24.

A0402 **CFR 489.20(q)** The provider agrees, in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

A0404 **CFR 489.20(r)(2) and 498.24(j)(1-2)**

§489.20(r)(2)

The hospital (including both the transferring and receiving hospitals), must maintain a list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition.

§489.24(j)(1)

Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

§489.24(j)(2)(i)

The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.

§489.24(j)(2)(ii)

The hospital must have written policies and procedures in place to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

A0405 **CFR 489.20(r)(3)** The provider agrees, in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

- A0406 **CFR 489.24(a)** In the case of a hospital that has an emergency department, if any individual (whether or not eligible for Medicare benefits and regardless of ability to pay) comes by him or herself or with another person to the emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition by qualified medical personnel (as determined by the hospital in its rules and regulations), the hospital must provide for 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 examinations must be conducted by individuals determined qualified by hospital bylaws or rules and regulations and who meet the requirements of W482.55 concerning emergency services personnel and direction.
- A0431 **CFR 482.53(a)(2)** The qualifications, training, functions and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.
- A0438 **CFR 482.53(d)** The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.
- A0441 **CFR 482.53(d)(3)** The hospital must maintain records of the receipt and distribution of radio pharmaceuticals.
- A0442 **CFR 482.53(d)(4)** Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.
- A0451 **CFR 482.24(c)(1)** All patient medical record entries must be complete.
- A0452 **CFR 482.24(c)(1)** All patient medical record entries must be dated and timed.
- A0454 **CFR 482.24((c)(1)(i))** All orders must be dated and timed, by the ordering practitioner, except as noted in paragraph (c)(1)(ii) of this section.
- A0455 **CFR 482. 24(c)(1)(i)** All verbal orders must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in paragraph (c)(1)(ii) of this section.
- A0456 **CFR 482. 24(c)(1)(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.
- A0459 **CFR 482. 24(c)(2)(i)** All records must document, as appropriate, evidence of a medical history and physical examination completed no more than 30 days before or 24 hours after admission.
- A0460 **CFR 482. 24(c)(2)(i)(A)** The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission.
- A0466 **CFR 482. 24(c)(2)(v)** All records must contain properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.
- A0468 **CFR 482. 24(c)(2)(vii)** All records must include discharge summary with outcome of hospitalization, disposition of care and provisions for follow-up care.
- A0500 **CFR 482. 25(b)** In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

A0501 **CFR 482.25(b)(1)** All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

A0505 **CFR 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

A0629 **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 service and operations.

A0632 **CFR 482.21(b)(2)** The hospital must use the data collected to monitor the effectiveness and safety of services and quality of care.

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.

A0724 **CFR 482.41(c)(2)** Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

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.

A1011 **CFR 482. 24(c)(1)** All patient medical record entries must be authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

A1508 **CFR 482.66(b)** The resident has a right to a dignified existence, self determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including 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.

A1510 **CFR 482.66(b)(1)** The facility must inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of the items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

A1513 **CFR 482.66(b)(1)** The resident has the right, unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, to participate in planning care and treatment or changes in care and treatment.

A1537 **CFR 482.66(b)(4)** 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 is licensed or registered, if applicable, by the State in which practicing; and 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 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 is a qualified occupational therapist or occupational therapy assistant; or has completed a training course approved by the State.

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.

A2402 **CFR 489.20(q)** The provider agrees, in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

A2404 **CFR 489.20(r)(2) and 489.24(j)(1-2)**

§489.20(r)(2)

The hospital (including both the transferring and receiving hospitals), must maintain a list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition.

§489.24(j)(1)

Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

§489.24(j)(2)(i)

The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.

§489.24(j)(2)(ii)

The hospital must have written policies and procedures in place to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

A2405 **CFR 489.(r)(3)** The provider agrees, in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

A2406 **CFR 489.(r) and 489.24(c)** 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 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.

If an emergency medical condition is determined to exist, the hospital must 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.

Sanctions under this section for inappropriate transfer during a national emergency 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.

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.

Federal Certification Critical Access Hospitals:

C0153 **CFR 485.608(c)** The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

C0154 **CFR 485.608(d)** Staff of the CAH are licensed, certified, or registered in accordance with applicable State and local laws and regulations.

C0204 **CFR 485.618(b)(2)** The items available must include 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.

C0205 **CFR 485.618(c)(2)** The facility provides, either directly or under arrangement, services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

C0207 **CFR 485.618(d)** (1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner, with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section:

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(ii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph (d)(2)(ii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

C0222 **CFR 485.623(b)(1)** The CAH has housekeeping and preventive maintenance programs to ensure that all essential mechanical, electrical, and patient care equipment is maintained in safe operating condition.

C0223 **CFR 485.623(b)(2)** The CAH has housekeeping and preventive maintenance programs to ensure that there is proper routine storage and prompt disposal of trash.

C0224 **CFR 485.623(b)(3)** The CAH has housekeeping and preventive maintenance programs to ensure that drugs and biologicals are appropriately stored.

C0225 **CFR 485.623(b)(4)** The CAH has housekeeping and preventive maintenance programs to ensure that the premises are clean and orderly.

C0226 **CFR 485.623(b)(5)** The CAH has housekeeping and preventive programs to ensure that there is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

C0240 **CFR 485.627** The CAH must ensure that specific organizational structure requirements are met.

- 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 in a safe environment.
- C0256 **CFR 485.631(b)** The CAH must ensure that specific responsibilities of the Doctor of Medicine or Osteopathy requirements are met.
- C0257 **CFR 485.631(b)(1)(i)** The doctor of medicine or osteopathy provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff.
- C0271 **CFR 485.635(a)(1)** The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.
- C0276 **CFR 485.635(a)(3)(iv)** The policies include 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. This regulation commonly cited when outdated drugs are not separated from those available for administration to patients, not keeping accurate records for scheduled drugs, and allowing unauthorized personnel access to pharmacy.
- C0279 **CFR 485.635(a)(3)(vii)** The policies include, if the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §485.25(i) is met with respect to inpatients receiving post-hospital SNF care.
- 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.
- C0283 **CFR 485.635(b)(3)** Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.
- 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.
- 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. 633(a)(2)** The records are legible, complete, 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, 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, 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.

This regulation commonly cited for not safeguarding the confidentiality of patient information. At times, this is in the medical records department when staff leaves the department and do not secure the records. Often it is cited when records or documentation containing patient names, diagnoses etc. are found accessible to unauthorized individuals in Radiology, Lab, Business Office, and other areas.

C0321 **CFR 485. 639(a)** The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by a doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; a doctor of dental surgery or dental medicine; or a doctor of podiatric medicine.

C0333 **CFR 485.641(a)(1)(ii)** The evaluation includes review of a representative sample of both active and closed clinical records.

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.

C0361 **CFR 485.645(d)(1)** The resident has a right to a dignified existence, self determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including 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.

C0364 **CFR 485.645(d)(1)** The resident has the right to choose a personal attending physician.

C0366 **CFR 485. 645(d)(1)** The resident has a right, unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, to participate in planning care and treatment or changes in care and treatment.

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.

C0371 **CFR 485. 645(d)(1)** The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights and safety of other residents.

C0372 **CFR 485. 645(d)(1)** The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

C0374 **CFR 485. 645(d)(2)** The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; or the transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; or the safety of individuals in the facility is endangered; or the health of individuals in the facility would otherwise be endangered; or the resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility.

For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or the facility ceases to operate.

C0377 **CFR 485. 645(d)(2)** Before a facility transfers or discharges a resident, the facility must notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand; record the reasons in the resident's clinical record; and include in the notice the items described in paragraph (a)(6) of this section.

C0378 **CFR 485. 645(d)(2)** Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

Notice may be made as soon as practicable before transfer or discharge when the safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section; or the health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section; or the resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section; or an immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or a resident has not resided in the facility for 30 days.

C0379 **CFR 485. 645(d)(2)** The written notice specified in paragraph (a)(4) of this section must include the following.

- o The reason for transfer or discharge;
- o The effective date of transfer or discharge;
- o The location to which the resident is transferred or discharged;
- o A statement that the resident has the right to appeal the action to the State; and
- o The name, address and telephone number of the State long term care ombudsman.
- o For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act.

o For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy for mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

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--

(i) Is a qualified therapeutic recreation specialist or an activities professional who--

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) 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

(ii) 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

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

C0388 **CFR 485. 645(d)(6)** The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

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

Identification and demographic information;

Customary routine;

Cognitive patterns;

Communication;

Vision;

Mood and behavior patterns;

Psychosocial well-being;

Physical functioning and structural problems;

Continence;

Disease diagnoses and health conditions;

Dental and nutritional status;

Skin condition;

Activity pursuit;

Medications;

Special treatments and procedures;

Discharge potential;

Documentation of summary information regarding the additional assessment performed through the resident assessment protocols; and

Documentation of participation in assessment.

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

C0389 **CFR 485. 645(d)(6)** A facility must conduct a comprehensive assessment of a resident within 14 calendar days after admission, excluding readmissions in which there is no significant change in the

resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

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.

State and Federal Certification for Ambulatory Surgical Centers:

S0140 **KAR 28-34-52(a)(7)** At a minimum, each facility shall ensure that each patient has a right to the following:

(7) be informed of the facility's policies regarding patient rights.

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(c)** 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.

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.

S0530 **KAR 28-34-58a(a)** Each ambulatory surgical center shall establish and maintain an ongoing infection control program. The program shall be based upon guidelines established by the centers for disease control and the licensing department. . . .

S0570 **KAR 28-34-58a(a)(8)** The program shall include the following:

(8) provisions for reporting, to the licensing department, infectious or contagious diseases in accordance with K.A.R. 28-1-2.

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.

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.

Q0021 **CFR 416.48(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.

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

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.

R0810 **KAR 28-52-1(e)(4)(E)** Plan format. Each submitted plan shall include the following:
Section IV E) mechanism for ensuring quarterly reporting of incident reports to proper licensing agency;

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.

R0815 **KAR 28-52-1(i)** Plan publication. The plan shall be disseminated to personnel in accordance with the plan.

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.

R0826 **KAR 28-52-2(b)** (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.

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.

R0834 **KAR 28-52-4(b)** Any incident determined by the designated risk management committee to meet category (a)(3) or (a)(4) shall be considered a "reportable incident" and reported to the appropriate licensing agency in accordance with KSA 65-4923.

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.

R0836 **KAR 28-52-4(c)** Those cases in which documented primary review by individual clinicians or subordinate committees does not occur, standard-of-care determinations shall be documented in the minutes of the designated committee on a case-specific basis.