Kansas Department of Health and Environment
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Annual Risk Management Report for 2006

"The Triumphs and Challenges of Emergency Medicine"

Emergency medicine ranges from a simple bandage (with maybe a kiss to make the pain go away) to a life threatening condition requiring human capabilities and technology to be taxed to the maximum. Regardless of your setting, you must be alert and prepared to provide emergency interventions, within your capabilities, at any time, not only to your patients, but also to staff and visitors.

Emergency medicine, like healthcare in general, continues to make huge strides that have changed the way we provide care and improved tremendously the potential for full recovery from even life threatening situations. Health care may not have obtained the technology level depicted on "Star Trek," but many milestones have been reached.

In the 1950s, many people contracted polio. Not only did the paralysis affect their ability to walk, but also many were unable to breathe on their own. "Iron lungs" were utilized and at times were in short supply. The patient was placed in the iron lung with only their head exposed and the intermittent negative press created in the chamber caused the patient to breathe. By the 1970s, ventilators were in common uses. They were portable and many were the size of an apartment size refrigerator. As with many devices, the ventilators have seen many revisions, their size has shrunk as performance improved. Now, disposable ventilators are available.

In the 1960s, the cutting edge protocol for cardiac and respiratory arrest was CPR (CardioPulmonary Resuscitation). The first step after determining cardiac and respiratory arrest was to administer a thump mid-sternum (breastbone) with the belief that this might restart the heart. Unfortunately, the thump caused fractured ribs and occasional sternum fractures in some patients. After a few years, the thump was eliminated from the CPR protocol. Over the years, the protocol continues to be refined. Currently, there is much talk of the benefits of cardiac percussions without providing respiratory support.

About 1980, a new phrase was circulating, “warm and dead” in regards to persons with hyperthermia, especially in situations of cold water drowning. At a hospital in Southeast Kansas, a CRNA (Certified Registered Nurse Anesthetist) read an article about the new theory. Shortly after reading the article, the CRNA was finishing post-operative anesthesia rounds at the hospital on a cold, mid-December afternoon when a car sped into the emergency drive. The car contained distraught adults and a small unresponsive boy. The adults explained that the child had fallen into a partially frozen farm pond and was under water for approximately 20 minutes prior to rescue. They had put the child in the car and drove as fast as roads would allow to the hospital. The drive took 30 minutes. No emergency interventions were given to the small boy prior to their arrival at the hospital. The boy had not vital signs. He had bluish skin, was very cold to the touch. He was considered clinically dead. The CRNA rapidly told the emergency team about the article he had recently read. The theory was put to the test. As staff started CPR and re-warming protocols, they began to monitor the boy’s temperature rectally. The initial temperature was in the mid 80s. As he began to warm up, his heart began to beat, later he started breathing on his own, and then he woke up. Once the endotracheal tube (breathing tube) was removed, he asked for something to eat. Due to the lack of oxygen for approximately an hour, the health team was concerned that he had suffered irreversible brain damage. The boy was monitored closely. At the delight of everyone, he showed no signs of any residual damage. He grew to manhood, married, and had a family. He led a very normal, productive life. The theory worked! In cases of hyperthermia, patients are no longer pronounced dead due purely to the absence of vital signs. Warm and dead has become the standard in these situations.

Healthcare workers are always on the lookout for ways to improve protocols and procedures. Twenty years ago, defibrillators were found in critical care settings and on code blue carts. Several years ago, physicians began implanting mini defibrillators directly in patients prone to life threatening cardiac irregularities. Today defibrillators are becoming commonplace in schools, airports, and office buildings for use by lay people.

For many years, lengthy waiting times between arrival and receipt of care has been a common concern for emergency departments. Debra Wood RN (July 30, 2007 NurseZone) noted that patients have better outcomes in most “wired” hospitals. Hospitals are turning to technology to assist in the delivery of quality care in a safe manner. Many hospitals have been creative and innovative in their approach to conquer this problem. In a 6/20/07 news release, Parkland Memorial Hospital Emergency Services Department, Dallas, Texas, reported on a new self-service check-in for Emergency Room patients in the triage area. They call the new check-in stations MediKiosks, which are available to patients in both English and Spanish. They use a computer touch screen similar to those used in airports to facilitate check-in. The information is sent to a main computer system under constant nurse surveillance. Emergency technicians and paramedics are available to respond to questions and emergent medical needs. Parkland Emergency Room handles more than 146,000 visits each year and feels that the system allows staff to better manage patient care by selecting patients based on medical criteria versus waiting time.

Regardless of the available technology and staff expertise, care does not always meet acceptable standards. The requirement for a Medical Screening Examination is not new, yet failure to meet this requirement was cited eight times, in Kansas during 2006. Occasionally, staff that completed the exam were not qualified to perform the task. More frequently, staff failed to complete the medical screening examination.

Another issue is problems with communications. The June 2007 *International Journal of Medical Informatics* reported on a case study conducted in a Level One Trauma Center at a teaching hospital. Not surprisingly, they noted that one-third of the Emergency Department communications meet the definition of interruptions and that this form of communication contributes to medical errors. This study noted that physicians were interrupted more than 10 times per hour and that registered nurses were interrupted almost 12 times per hour. The study found that people interrupt more frequently than technology. The study concluded that the research provided a better understanding of the Emergency Department workflow interruptions, the identification of work constraints, and the need to develop effective interventions to manage the interruptions.

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 released. According to the article, a 43 year-old female was described as "bleeding from the mouth and writing in pain," as she waited in the hospital waiting area. The Los Angeles Times obtained and release the recordings of two 911 calls, where 911 dispatchers repeatedly referred the callers to hospital staff and refused to provide assistance. The common questions are "What went wrong?" and "How could this happen?" We may never have the answers. However, if even one hospital identifies similar issues and makes corrective action, as a result of this death, the death will not be in vain.

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.

Kansas is also one of the few states that assess hospital infection control via a mandatory Risk Management program. All hospital-acquired infections are incidents the hospital must investigate, make a standard of care determination, and report substandard care to the appropriate licensing board.

Another 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.

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. 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 2006.

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 nine years since this book was published. 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. This would include minor injuries as well as the more severe. 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 twentieth 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 in 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 fils to improve. These teams are empowered to “take charge” of the patient’s care, if indicated.

“Effective Risk Management” (submitted in 2004) emphasized the importance of a proactive risk management program. According to an April 2005 AARP (American Association of Retired Persons) bulletin, only 10% 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 in 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.

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 mandates that the states:

1) complete 5% targeted ASC surveys each year for compliance with federal regulations, in tier two;

2) complete additional surveys to insure that no more than seven years elapses between surveys of any one ASC provider, in tier three; and
3) ensure that all ASC providers are surveyed at least every six years, on average, in tier four.

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, 2006, there were fifty-eight 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 5% 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, in tier two;
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, in tier three; and
3) ensure that all non-accredited hospital or non-accredited critical access hospital are surveyed at least every three years, on average, in tier four.

Kansas continues to lead the states in the number of CAHs. As of December 31. 2006, 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 2006, 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 2007

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
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

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Appendices

Frequently Cited Tags

Glossary of Terms

AHRQ…….Agency for Healthcare Research and Quality
ASC .....…….Ambulatory Surgical Center
BCCHF .....……..Bureau of Child Care and Health Facilities
CAH .....……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
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 – 2006

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%)	22(4.1%)	32(6%)	166(31.3%)

***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.

Table 2

Comparison of Total Number of **Reportable Incidents** Generated By Facility Size and Licensing Agency
1996-2006

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
1-25 beds	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 or 13.6%	79 or 56.5 %	32 or 22.8%	8 or 5.7 %	1 or 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	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	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%
	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%

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
	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	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	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
ASCs	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

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
	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 – 2006

Facilities by Bed Size/ Category	Number of Facilities in Size Category 2006	Avg # of SOCs/ Total # of Reportable SOCs Reviewed 2000	Avg # of SOCs/ Total # of Reportable SOCs Reviewed 2001	Avg # of SOCs/ Total # of Reportable SOCs Reviewed 2003	Avg # of SOCs/ Total # of Reportable SOCs Reviewed 2004	Avg # of SOCs/ Total # of Reportable SOCs Reviewed 2005	Avg # of SOCs/ Total # of Reportable SOCs Reviewed 2006
1 - 25	93	218/97	213/97	238/140	264.3/127	296.9/169	351/176
26 - 50	12	373/102	362/71	385/75	413.8/51	492.8/30	501.8/31
51 - 100	24	591/86	485/38	568/88	606/45	555.8/77	596.8/67
101 - 200	12	906/7	780/55	1097/60	1009/108	703.4/43	1049/36
200 +	13	2093/242	2057/191	2803/201	208.9/179	2873/313	3044/201
ASCs	58	24/5	28.5/0	33.7/0	29.8/9	39.6/8	37/20
Totals	212	/571	/436	436.8/564	427/519	469.5/640	506.1/531

*__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 75,0000 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 % misusage. 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.

APPENDIX A

Total of Survey Codes Cited During 50 **Acute Care Hospital** Licensure/Certification Surveys 2006

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
H0009	1	A0072	1	A0389	1
H0014	1	A0073	1	A0392	1
H0031	1	A0143	1	A0400	6
H0033	1	A0184	1	A0400	2
H0042	2	A0185	1	A0405	2
H0044	1	A0201	1	A0406	8
H0054	1	A0204	9	A0407	1
H0063	1	A0205	9	A0421	1
H0113	2	A0206	1	A0421	1
H0114	3	A0212	1	A1508	1
H0149	1	A0223	2	A1510	1
H0150	1	A0227	3	A1513	1
		A0230	5	A1514	1
A0021	1	A0234	1	A1515	1
A0028	1	A0238	1	A1516	1
A0041	1	A0239	2	A1519	1
A0053	1	A0241	1	A1526	1
A0056	2	A0254	4	A1527	1
A0057	1	A0255	2	A1537	1
A0059	2	A0269	1	A1541	1
A0060	1	A0270	1		
A0063	1	A0297	1		
A0064	1	A0318	1		
A0066	2	A0331	2		
A0067	1	A0339	1		
A0069	1	A0340	1		
A0070	1	A0363	2		

APPENDIX B

Total of Survey Codes Cited During 6 Critical Access Hospital Certification Surveys 2006

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
C0153	1	C0283	2	C0334	2
C0154	1	C0291	1	C0336	1
C0195	1	C0294	1	C0337	1
C0207	3	C0298	2	C0338	1
C0222	1	C0030	1	C0385	1
C0225	1	C0302	1		
C0229	1	C0303	1		
C0241	1	C0304	1		
C0257	1	C0307	2		
C0258	1	C0308	2		
C0260	1	C0309	1		
C0270	1	C0310	1		
C0271	1	C0320	1		
C0272	2	C0321	1		
C0275	1	C0322	1		
C0276	4	C0330	1		
C0278	1	C0331	2		
C0280	2	C0332	1		
C0281	1	C0333	2		

APPENDIX C

Total of Survey Codes Cited During 34 **Ambulatory Surgical Center** Licensure and Certification Surveys 2006

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
Q0003	1	Q0030	1	S0575	1
Q0006	1			S0580	1
Q0009	1	S0140	9	S0610	1
Q0011	2	S0365	1	S0615	1
Q0014	1	S0370	1	S0620	1
Q0019	1	S0375	1	S0840	1
Q0020	2	S0380	1	S0845	1
Q0021	1	S0530	1		
Q0022	1	S0550	1		
Q0027	1	S0560	1		

APPENDIX D

Total of Survey Codes cited During 14 Hospital, CAH and ASC **Risk Management** Surveys 2006

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
R0801	2	R0819	1	R0832	2
R0802	1	R0820	1	R0833	6
R0803	1	R0826	1	R0835	1
R0810	1	R0827	1		
R0812	1	R0828	4		
R0813	2	R0829	2		
R0815	2	R0831	3		

APPENDIX E

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 50 **Hospital** Certification & Licensure 2006

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
A0204 – RN Supervision of Nursing Care	9	18%
A0406 – Medical Screening Exam	8	16%
A0400 – Compliance with CFR 489.24	6	12%
A0254 – Locked Storage Area	4	8%

APPENDIX F

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 6 **CAH Hospital** Certification Surveys 2006

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
C0207 - Personnel	3	50%
C0272 – Patient Care Policies	2	33.3%
C0283 - Radiology	2	33.3%
C0298 – Nursing Services – Care Plans	2	33.3%
C0308 – Protection of Record Information	2	33.3%

APPENDIX G

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 11 **Hospital & CAH** Risk Management Surveys 2006

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
R0833 – Separate SOC per provider and clinical issue	4	36.4%
R0829 – Documentation of risk management committee activities	3	27.3%
R0831 – SOC categories compliant with regulations	2	18.2%
R0832 – Appropriate SOC determination	2	18.2%

APPENDIX H

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During **ASC** Surveys – 34* Certification & Licensure and 3 Risk Management Surveys 2006
*Includes 14 initial surveys

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
Q0011 – Physical Environment	2	5.9%
Q0020 – Membership and Clinical Privileges	2	5.9%
S0140 – Patient Rights	9	26.5%
R0833 – Separate SOC per provider and clinical issue	2	66.7%

APPENDIX I

2006 Cited Survey Codes

State Licensure and Federal Certification Acute Care Hospital:

H0009 **KAR 28-34-3b(a)** The governing body shall ensure that the facility establishes policies and procedures which support the rights of all inpatients and outpatients.

H0011 **KAR 28-34-3b(b)** The facility's policies and procedures shall establish a mechanism for responding to patient complaints.

H0014 **KAR 28-34-5a** Governing body. Each hospital shall have an organized governing body. The governing body shall be the ultimate authority in the hospital responsible for its organization and administration in a manner which is consistent with appropriate standards of patient care, environmental safety and institutional management.

H0031 **KAR 28-34-7(e)** All licensed practical nurses and nursing staff shall be under the supervision of a registered nurse.

H0033 **KAR 28-34-7(g)** Nursing care policies and procedures shall be in writing and consistent with generally accepted practice and shall be reviewed and revised as necessary.

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

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

H0054 **KAR 28-34-9a(d)(5)** Each record shall be treated as confidential. Only persons authorized by the governing body shall have access to the records. These persons shall include individuals designated by the licensing agency for the purpose of verifying compliance with state or federal statutes or regulations and for disease control investigations of public health concern.

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.

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.

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.

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.

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).

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.

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.

A0063 **CFR 482.13(e)** The hospital must ensure that specific restraint for acute medical and surgical care requirements are met.

A0064 **CFR 482.13(e)(2)** A restraint can only be used if needed to improve the patient's well being and less restrictive interventions have been determined to be ineffective.

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.

A0067 **CFR 482.13(e)(3)(ii)(A)** The order for restraint must never be written as a standing or on an as needed basis (that is, PRN).

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.

A0070 **CFR 482.13(e)(3)(iv)** The use of a restraint must be implemented in the least restrictive manner possible.

A0072 **CFR 482.13(e)(3)(vi)** The use of a restraint must be ended at the earliest possible time.

A0073 **CFR 482.13(e)(4)** The condition of the restrained patient must be continually assessed, monitored and reevaluated.

A0143 **CFR 482.21(a)(1)** The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes.

A0184 **CFR 482.22(a)(2)** The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

Deficiency commonly cited when governing body credentials candidates without medical staff input.

A0185 **CFR 482.22(b)** There must be administrative and technical personnel competent in their respective duties.

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.

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.

A0212 **CFR 482.23(c)(2)(ii)** When telephone or oral orders must be used, they must be signed or initialed by the prescribing practitioner as soon as possible.

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.

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.

A0234 **CFR 482.24(c)(2)(ii)** All records must document evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

A0238 **CFR 482.24(c)(2)(v)** All records must include 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.

A0239 **CFR 482.24(c)(2)(vi)** All records must include all practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

A0240 **CFR 482.41(c)** Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

A0241 **CFR 482.24(c)(2)(viii)** All records must include final diagnosis with completion of medical records within 30 days following discharge.

A0254 **CFR 482.25(b)(2)** Drugs and biologicals must be kept in a locked storage area.

A0269 **CFR 482.26(b)** The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

A0270 **CFR 482.26(b)(1)** Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

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.

A0363 **CFR 482.43(d)** The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

A0389 **CFR 482.51(a)(4)** Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

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.

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.

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.

A0407 **CFR 489.24(c)(1)** If any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either, within the capabilities of the staff and facilities available at the hospital,

For FURTHER MEDICAL EXAMINATION AND TREATMENT as required to stabilize the medical condition; or for transfer of the individual to another medical facility in accordance with paragraph (d) of this section.

Refusal to consent to treatment.

A hospital meets the requirements of paragraph (c)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) refuses to consent to the examination and treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting in his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

A0421 **CFR 482.52(b)(3)** The policies must ensure that, with respect to inpatients, a post-anesthesia follow-up report by the individual who administers the anesthesia that is written within 48 hours after surgery is provided for each patient.

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.

A1514 **CFR 482. 66(b)(1)** The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility.

The resident's right to refuse release of personal and clinical records does not apply when the resident is transferred to another health care institution; or record release is required by law.

A1515 **CFR 482.66(b)(1)** The resident has the right to refuse to perform services for the facility; 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.

A1516 **CFR 482.66(b)(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.

A1519 **CFR 482.66(b)(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.

A1526 **CFR 482.66(b)(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.

A1527 **CFR 482.66(b)(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.

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.

A1541 **CFR 482.66(b)(6)** When the facility anticipates discharge a resident must have a discharge summary that includes a recapitulation of the resident's stay; a final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and a post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

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.

C0195 **CFR 485.616(b)** Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least one hospital that is a member of

the network; one QIO or equivalent entity, and one other appropriate and qualified entity identified in the State rural health care plan.

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.

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

C0229 **CFR 485.623(c)(3)** The CAH assures the safety of patients in non-medical emergencies by providing for emergency power and lighting in the emergency room and for battery lamps and flashlight in other areas.

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.

C0258 **CFR 485.631(b)(1)(i)** The doctor of medicine or osteopathy, in conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

C0260 **CFR 485.631(b)(1)(iv)** The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes.

C0270 **CFR 485.635** Provision of services

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.

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

C0275 **CFR 485.635(a)(3)(iii)** The policies include guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

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.

C0277 **CFR 485.635(a)(3)(v)** The policies include procedures for reporting adverse drug reactions and errors in the administration of drugs.

C0278 **CFR 485.635(a)(3)(vi)** The policies include a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

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

C0281 **CFR 485.635(b)(1)** The CAH staff furnishes as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

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.

C0294 **CFR 485.635(d)** Nursing services must meet the needs of patients.

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

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.

C0302 **CFR 485. 633(a)(2)** The records are legible, complete, accurately documented, readily accessible, and systematically organized.

C0303 **CFR 485.633(a)(3)** A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

C0304 **CFR 485.638(a)(4)(i)** For each patient receiving health care services, the CAH maintains a record that includes, as applicable, 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.

C0309 **CFR 485.638(b)(2)** Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

C0310 **CFR 485.638(b)(3)** The patient's written consent is required for release of information not required by law.

C0320 **CFR 485.639** Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

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.

C0322 **CFR 485.639(b)** A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed. A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia. Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

C0330 **CFR 485.641** Periodic evaluation and quality assurance review.

C0331 **CFR 485.641(a)(1)** The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year.

C0332 **CFR 485.641(a)(1)(i)** The evaluation includes review of the utilization of CAH services, including at least the number of patients served and the volume of services.

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

C0334 **CFR 485.641(a)(1)(iii)** The evaluation includes review of the CAH's health care policies.

C0336 **CFR 485.641(b)** The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes.

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.

This regulation is frequently cited when facilities do not evaluate patient care provided by direct care staff and contracted staff. This also applies to contracted services conducted off site (for example, laundry, radiology interpretation, etc).

C0338 **CFR 485.641(b)(2)** The quality assurance program requires that nosocomial infections and medication therapy 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.

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.

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.

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

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

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

S0380 **KAR 28-34-56a(a)** If there is a department of anesthesia, it shall be directed by a member of the medical staff with appropriate clinical and administrative experience. . .

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. . . .

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

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

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

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

S0610 **KAR 28-34-58a(e)** Soiled and clean linen shall be handled and stored separately.

S0615 **KAR 28-34-58a(f)** All garbage and waste shall be collected, stored, and disposed of in a manner that does not encourage the transmission of contagious disease. Containers shall be washed and sanitized before being returned to work areas, or the containers may be disposable.

S0620 **KAR 28-34-58a(g)** Staff shall make periodic checks, according to the facility's policies and procedures, throughout the premises to enforce sanitation procedures.

S0840 **KAR 28-34-61a(d)(1)** Fire and disaster drills. Each ambulatory surgical center shall meet the following requirements:

(1) Develop a written fire evacuation plan. Drills shall be held according to the facility's policies and procedures to prepare employees for evacuation of patients, staff, and visitors during a fire emergency. A record of each drill shall be kept on file.

S0845 **KAR 28-34-61a(d)(2)** Fire and disaster drills. Each ambulatory surgical center shall meet the following requirements:

(2) Develop a written plan for addressing the safety of patients, staff, and visitors during disasters. Periodic drills shall be held, and a record of each drill shall be kept on file.

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

Q0006 **CFR 416.42(a)** A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ambulatory surgical center, each patient must be evaluated by a physician for proper anesthesia recovery.

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.

Q0011 **CFR 416.44** The ambulatory surgical center must provide a functional and sanitary environment for the provision of surgical services.

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

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

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

Q0021 **CFR 416.48(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.

Q0027 **CFR 416.47(b)** The ambulatory surgical center must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include, at least, the following:

- Patient identification
- Significant medical history and results of physical examination
- Pre-operative diagnostic studies (entered before surgery), if performed

- Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.
- Any allergies and abnormal drug reactions
- Entries related to anesthesia administration
- Documentation of properly executed informed patient consent
- Discharge diagnosis.

Q0030 **CFR 416.48(a)** Drugs must be prepared and administered according to established policies and acceptable standards of practice.

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.

R0803 **KAR 28-52-1(d)** All patient services including those services provided by outside contractors or consultants shall be periodically reviewed and evaluated in accordance with the 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;

R0812 **KAR 28-52-1(e)(6)** Plan format. Each submitted plan shall include the following:
Section VI - documentation that the plan as submitted has been approved by the facility's governing body.

R0813 **KAR 28-52-1(e)(6)** Plan submittal. On and after November 1, 1986, each medical care facility shall submit the plan to the department at least 60 days prior to the license renewal date. After an initial plan is approved, any amendments to the plan shall be submitted to the department.

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.

R0827 **KAR 28-52-2(c)** Incident reports, investigational tools, minutes of risk management committees, and other documentation of clinical analysis for each reported incident shall be maintained by the facility for not less than one year following
completion of the investigation.

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

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

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

R0831 **KAR 28-52-4(a)(1-4)** Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:
(1) Standards of care met;
(2) Standards of care not met, but with no reasonable probability of causing injury;
(3) Standards of care not met, with injury occurring or reasonably probable; or
(4) possible grounds for disciplinary action by the appropriate licensing agency.

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

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

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

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