



Kansas Department of Health and Environment  
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## **Annual Risk Management Report for 2005**

### **“Putting the Patient’s Safety First”**

Many facilities have mission statements including the provision of ultimate care to all patients. To accomplish this, you must put patient safety first. Healthcare providers would like for each patient’s visit to be a “road to recovery.” In actuality, many patients’ visits are more likely to resemble an obstacle course strewn with infections, medication errors, missed diagnoses, omitted treatments, etc.

Mission 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,” you need to evaluate priorities and give patient care and patient safety its rightful place.

Unless your facility has a wealthy benefactor or a genie in a bottle, you must consider the financial aspect of any endeavor. But cost is just one aspect in every decision – from basic supplies to state-of-the-art equipment to expansion or reduction of services. Are you enlisting the input of end-user staff? Are you standardizing service points – patient rooms, crash carts, supply carts, etc? Or do your carts, rooms, etc vary from unit to unit, hall to hall, room to room? The defibrillators, infusion pumps, and other key pieces of equipment in many facilities are a variety of brands and models. Some are not user friendly, which can often be identified by the “post-it” notes hung on or near the equipment to cue staff on how to operate the equipment. All of these factors cost precious time and increase the potential for mistakes. These factors do not put patient safety first.

Medication errors continue to be a common adverse event. During the past year, we have noted an increase in medication errors related to staff using the override option on automated dispensing machines. In the June 2006 Hospital Pharmacy, an article entitled, “Errors Associated with Medications Removed from Automated Dispensing Machines Using Override Function” reported the following findings:

- 10% of the overrides lacked written physician orders corresponding to the medication
- 2% of the overrides involved medication errors or near misses, including two doses administered after the drug was discontinued and one dose administered the day before it was to be started

According to the article, the researchers concluded that errors were more likely to occur when all medication were available for removal versus when only emergency, pre-procedural, and intravenous pain medications were available using a critical override option. A possible solution to reduce errors further is the requirement of a witness for these critical overrides.

Hospital acquired (nosocomial) infections are considered adverse events and must be investigated through risk management. Federal regulations - CFR 416.44(a)(3), 482.42(a)(2), 485.635(a)(3)(vi), and 485.641(b)(2) - require that all infections be identified, logged, and/or evaluated. Findings during surveys and risk management trainings confirm that some hospitals are still not compliant with these requirements.

Hospital acquired infections has been become a focus area for all concerned with quality health care. We have assessed, in cooperation with the hospital industry how best to decrease rates of infection, including evaluation of existing state and federal regulations. We do not think additional regulations specific to infection control procedures is the answer. We believe the most effective approach is that being pursued by the Centers for Disease Control, which is public disclosure by hospitals of infection rates.

Prevention and control of infections is an integral part of KDHE oversight of hospitals. Existing regulations require hospitals to provide a sanitary environment and have an active program to prevent, control and investigate infections. Evaluating compliance is built into our survey protocol and is part of every hospital survey, or in response to a complaint.

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.

The Centers for Disease Control will be making available in the next year a national reporting system we think will provide meaningful information, on individual hospital infection rates, to consumers and regulators. We believe this will have a very positive impact on infection rates.

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.

Your risk management program should be proactive. Your program 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 for possible revision. Many aspects of patient safety and “just culture” are being considered for inclusion. Everyone wants to be 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 organizations/agencies 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 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 2005.

The book To Error 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. Yet, in Kansas we continue to have wrong site surgeries. These recommendations included that the surgical site is marked during the educational process and prior to surgery and that all members of the surgical team take an active part is assuring the site is correct. It has been seven 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. 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 recently 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.

“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.

### *Ambulatory Surgical Centers*

KDHE implemented the new certification, licensure and risk management survey process for ASCs in the spring of 2001 using the new state regulations approved in April 2001. CMS mandates that the states survey at least 17% of the ASCs each year for compliance with federal regulations.

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, 2005, there were fifty-three 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.

Kansas continues to lead the states in the number of CAHs. As of December 31, 2005, there were 84 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 so that Kansas has a more universal reporting system and to work on developing better 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. The Risk Management Specialist is available to provide education for the medical care facilities. Compliance with two of the statutes continues to challenge facilities. These areas are the confidentiality of information and minimizing occurrences. Many Kansas facilities had a changeover of risk managers during the interim between surveys. New risk managers and some 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 Error is Human: Building a Safer Health System, 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 2005, 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.

Hospitals with swing beds were required to complete a Swing Bed MDS (Minimum Data Set) beginning in July 2002 to establish reimbursement for Medicare recipients. CAHs with swing beds were not required to complete Swing Bed MDS. Training was conducted on the Swing Bed MDS process and the differences between hospitals with swing beds and CAHs with swing beds. During the survey process, surveyors have cited both hospitals with swing beds and CAHs for failing to:

- 1) fully assess patients,
- 2) protect patient records from unauthorized use, and/or
- 3) implement a quality assurance program.

#### *Risk Management Goals for 2006*

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***

## ***Tables***

## ***Appendices***

## ***Frequently Cited Tags***

## ***Glossary of Terms***

<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>ASC</b>	Ambulatory Surgical Center
<b>BCCHF</b>	Bureau of Child Care and Health Facilities
<b>CAH</b>	Kansas Administrative Regulations
<b>CDC</b>	Centers for Disease Control
<b>CFR</b>	Code of Federal Regulations
<b>CMS</b>	Centers for Medicare and Medicaid Services
<b>KARQM</b>	Kansas Association of Quality and Risk Managers
<b>KDHE</b>	Kansas Department of Health and Environment
<b>KHA</b>	Kansas Hospital Association
<b>KSA</b>	Kansas Statutes Annotated
<b>KSBHA</b>	Kansas State Board of Healing Arts
<b>KSBN</b>	Kansas State Board of Nursing
<b>KSPB</b>	Kansas State Pharmacy Board
<b>MDS</b>	Minimum Data Set
<b>NCPS</b>	National Center for Patient Safety
<b>SB MDS</b>	Swing Bed Minimum Data Set
<b>SOC</b>	Standard of Care
<b>TAGS</b>	(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 – 2005

Year	Total # of Reported Incidents	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%)

**\*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 2<sup>nd</sup> quarter 1998. It did slowly increase in 3<sup>rd</sup> and 4<sup>th</sup> 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 incidents by all providers was 93,627 with 501 SOC IIIs and SOC IVs or .535%.

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

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

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

**Table 2**

Comparison of Total Number of **Reportable Incidents** Generated By Facility Size and Licensing Agency  
1996-2005

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
1-25 beds	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	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	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%
	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%

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
	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	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	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	2005	2 or 25%	3 or 37.5%	3 or 37.5%	0	0
	2004	2 or 29%	3 or 43%	2 or 28%	0	0
	2003	0	0	0	0	0
	2002	1 or 8%	0	3 or 23%	0	9 or 69%
	2001	0	0	0	0	0
	2000	2 or 40%	0	0	0	3 or 60%
	1999	0	0	1 or 100%	0	0
	1998	0	0	0	0	0
	1997	0	2 or 100%	0	0	0

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
	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 – 2005

Facilities by Bed Size/Category	Number of Facilities in Size Category 2005	Avg # of Incidents/ Total # of Reportable Incidents Reviewed 2000	Avg # of Incidents/ Total # of Reportable Incidents Reviewed 2001	Avg # of Incidents/ Total # of Reportable Incidents Reviewed 2003	Avg # of Incidents/ Total # of Reportable Incidents Reviewed 2004	Avg # of Incidents/ Total # of Reportable Incidents Reviewed 2005
1 - 25	93	218/97	213/97	238/140	264.3/127	296.9/169
26 - 50	10	373/102	362/71	385/75	413.8/51	492.8/30
51 - 100	27	591/86	485/38	568/88	606/45	555.8/77
101 - 200	11	906/7	780/55	1097/60	1009/108	703.4/43
200 +	14	2093/242	2057/191	2803/201	208.9/179	2873/313
ASCs	54	24/5	28.5/0	33.7/0	29.8/9	39.6/8
Totals	209	/571	/436	436.8/564	427/519	469.5/640

\***Table 3** above compares the average number of incidents reviewed and the total number of incidents 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 5 (c) and 5 (d) on the same form. The bed size is based on the acute bed count as determined by a facility's license. For example, a facility licensed for 20 acute beds and 60 long-term care beds would be included in the 1-25 bed grouping. Mental health, mental retardation, and psychiatric hospitals are listed by total bed count.



## KDHE RISK MANAGEMENT ARTICLES

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

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

## APPENDIX A

Total of Survey Codes Cited During 51 **Acute Care Hospital** Licensure/Certification Surveys 2005

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
H0010	1	A0067	2	A0214	2	A0338	4
H0038	1	A0069	2	A0221	2	A0339	3
H0042	2	A0070	2	A0223	4	A0340	4
H0044	5	A0072	1	A0225	2	A0341	3
H0093	1	A0073	2	A0227	2	A0342	4
H0113	1	A0141	2	A0229	1	A0363	1
H0114	1	A0142	2	A0230	5	A0389	1
H0149	1	A0145	2	A0231	2	A0390	1
H0150	1	A0151	2	A0232	2	A0391	1
		A0154	2	A0234	1	A0392	1
A0006	3	A0155	2	A0238	3	A0396	2
A0009	3	A0156	2	A0240	1	A0400	2
A0011	1	A0157	1	A0241	3	A0404	1
A0012	2	A0167	2	A0248	1	A0406	4
A0021	1	A0169	2	A0250	1	A0407	1
A0027	1	A0170	1	A0251	2	A0418	1
A0028	4	A0181	2	A0252	1	A0421	1
A0029	3	A0184	3	A0254	6	A0447	2
A0038	1	A0185	2	A0255	6	A0448	2
A0039	1	A0186	4	A0258	1	A0459	1
A0040	1	A0191	2	A0261	1	A0466	1
A0045	1	A0199	2	A0285	2		
0046	1	A0201	1	A0290	1		
A0056	1	A0204	10	A0296	1		
A0057	3	A0205	10	A0297	1		
A0058	2	A0207	3	A0317	2		
A0059	1	A0208	6	A0318	6		

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
A0060	3	A0209	1	A0321	1		
A0062	1	A0210	3	A0322	1		
A0065	1	A0211	1	A0326	2		
A0066	4	A0212	2	A0331	7		

## APPENDIX B

Total of Survey Codes Cited During 15 Critical Access Hospital Certification Surveys 2005

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
C0190	2	C0281	1	C0347	2
C0191	2	C0293	1	C0361	1
C0195	2	C0294	1	C0365	1
C0203	1	C0296	1	C0367	1
C0206	2	C0297	2	C0370	2
C0222	2	C0298	4	C0382	2
C0225	2	C0304	2	C0383	2
C0229	2	C0307	2	C0384	1
C0240	2	C0308	5	C0385	5
C0241	2	C0330	2	C0395	4
C0257	1	C0331	2	C0396	3
C0258	2	C0332	2	C0397	2
C0263	3	C0333	2	C0402	2
C0271	2	C0334	2		
C0272	4	C0335	2		
C0276	4	C0336	3		
C0279	3	C0337	3		
C0280	2	C0338	2		

## APPENDIX C

Total of Survey Codes Cited During 6 **Ambulatory Surgical Center** Licensure and Certification Surveys  
2005

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
Q0030	2	S0130	1	S0160	1
		S0145	1	S0260	1
S0110	1	S0150	1	S0330	1
S0115	1	S0155	1	S0575	1

## APPENDIX D

Total of Survey Codes cited During 15 Hospital, CAH and ASC **Risk Management** Surveys 2005

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
R0801	2	R0809	1	R0832	3
R0802	3	R0812	1	R0833	8
R0803	3	R0816	1	R0834	2
R0805	2	R0819	4	R0837	1
R0806	4	R0820	3		
R0807	2	R0822	1		
R0808	1	R0829	2		

## APPENDIX E

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 51 **Hospital** Certification & Licensure 2005

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
A0204 – RN Supervision of Nursing Care	10	20%
A0205 – Nursing Care Plan	10	20%
A0331 – Facilities, Supplies & Equipment	7	14%
A0208 – Administration of Drugs	6	12%
A0254 – Locked Storage Area	6	12%
A0255 – Unusable Drug Use	6	12%
A0318 – Maintenance of Physical Plant	6	12%

## APPENDIX F

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 15 **CAH Hospital** Certification Surveys 2005

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
C0225 - Maintenance	3	20%
C0204 – Equipment and Supplies	2	13%
C0272 – Patient Care Policies	2	13%
C0307 – Record System	2	13%
C0308 – Protection of Record Information	2	13%
C0385 – Quality of Life	2	13%
C0337 – Quality Assurance	2	13%

## APPENDIX G

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 12 **Hospital & CAH Risk** Management Surveys 2005

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
R0833 – Separate SOC per provider and clinical issue	8	67%
R0832 – Appropriate SOC determination	6	50%
R0802 – Findings, conclusions, recommendations, actions taken, and results documented and reported through procedures established with RM plan.	5	42%
R0801 – Plan approved and reviewed annually the governing body	4	33%
R0825 – Written acknowledgement of incident report receipt.	4	33%

## APPENDIX H

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 9 **ASC** Certification & Licensure/Risk Management Surveys 2005

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
Q0002 – Compliance with State Licensure	1	11%
Q0020 – Membership and Clinical Privileges	1	11%
S0155 – Patient Rights	1	11%
S0160 – Patient Rights	1	11%
S0375 – Human Resources	1	11%
S0845 – Physical Environment	1	11%
R0801 – Plan approved and reviewed annually by the governing body	1	11%
R0822 – Reports, records and proceedings confidential and privileged	1	11%
R0826 – Written acknowledgement of incident report receipt	1	11%
R0833 – Separate SOC per provider and clinical issue	1	11%

# APPENDIX I

## 2005 Cited Survey Codes

### State Licensure and Federal Certification Acute Care Hospital:

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

H0038 **KAR 28-34-8a(c)** Personnel policies and procedures. The governing body, through the chief executive officer, shall establish and maintain written personnel policies and procedures, which adequately support sound patient care. These policies and procedures shall be made available to all employees and shall be reviewed at least every two years. A procedure shall be established for advising employees of policy and procedure changes.

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.

H0093 **KAR 28-34-17b(a)** General provisions. Surgical services shall be provided in a manner sufficient to meet the medical needs of the patients. (b) Personnel: (1) The director of the surgical services shall be a qualified member of the medical staff with appropriate surgical and administrative experience.

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 radiant 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.

H0149           **KAR 28-34-22(e)** When a patient is referred to the physical therapy department, the treatment to be administered shall be recorded on the patient's chart, including all pertinent details of the treatment procedure.

H0150           **KAR 28-34-22(f)** Records of inpatients and outpatients treated in the physical therapy department shall be maintained. The date of each patient visit shall be recorded as well as modalities employed and the area or areas treated. Patient progress notes shall be maintained.

A0006           **CFR 482.12** The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

A0009           **CFR 482.12(a)(2)** The governing body must appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

A0012           **CFR 482.12 (a)(5)** The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

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.

A0027           **CFR 482.12(e)** The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

A0028           **CFR 482.12(e)(1)** The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

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

A0038           **CFR 482.13** The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

A0039           **CFR 482.13(a)** The hospital must ensure that specific notice of rights requirements are met.

A0040           **CFR 482.13a)(1)** A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

- A0046 **CFR 482.13a(2)(iii)** In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.
- A0055 **CFR 482.13(c)** The patient has the right to personal privacy.
- A0056 **CFR 482.13(c)(1)** The patient has the right to personal privacy.
- A0057 **CFR 482.13(c)(2)** The patient has the right to receive care in a safe setting.
- A0058 **CFR 482.13(c)(3)** The patient has the right to be free from all forms of abuse or harassment.
- A0059 **CFR 482.13(d)** Confidentiality of Patient Records Standard.
- A0060 **CFR 482.13(d)** The patient has the right to the confidentiality of his or her clinical records.
- A0062 **CFR 482.13(e)** The hospital must ensure that specific restraint for acute medical and surgical care requirements are met.
- A0065 **CFR 482.13(e)(3)(i)** The use of a restraint must be selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm.
- 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.
- A0141 **CFR 482.21** The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

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

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

- A0142 **CFR 482.21(a)** The hospital must ensure that specific program scope requirements are met.
- A0145 **CFR 482.21(a)(2)** The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.
- A0151 **CFR 482.21(c)** The hospital must ensure that specific QAPI program activities requirements are met.
- A0154 **CFR 482.21(c)(2)** Performance improvement activities must track medical errors and adverse patient events.
- A0155 **CFR 482.21(c)(2)** Performance improvement activities must analyze causes of medical errors and adverse patient events.
- A0156 **CFR 482.21(c)(2)** Performance improvement activities must implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
- A0157 **CFR 482.21(c)(3)** The hospital must take actions aimed at performance improvement.
- A0167 **CFR 482.21(e)** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that specific QAPI program requirements are met.
- A0170 **CFR 482.21(e)(2)** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and that all improvement actions are evaluated.
- A0181 **CFR 482.22** The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of care provided to patients by the hospital.
- 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.
- A0186 **CFR 482.22(c)** The medical staff must adopt and enforce bylaws to carry out its responsibilities.
- A0188 **CFR 482.28 (b)** Nutritional needs must be met in accordance with recognized practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patient.
- A0191 **CFR 482.22(c)(5)** The bylaws must include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

- A0199 **CFR 482.23** The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.
- 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.
- A0207 **CFR 482.23(b)(6)** Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel, which occur within the responsibility of the nursing services.
- A0208 **CFR 482.23(c)** Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.
- A0209 **CFR 482.23(c)(1)** All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.
- A0210 **CFR 482.23(c)(2)** All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under §482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications.
- A0211 **CFR 482.23(c)(2)(i)** When telephone or oral orders must be used, they must be accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law.
- 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.
- A0214 **CFR 482.23(c)(4)** Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.
- A0221 **CFR 482.24** The hospital must have a medical records service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.
- 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.

- A0225 **CFR 482.24(b)(2)** The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.
- A0227 **CFR 482.24(b)(3)** The hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.
- A0229 **CFR 482.24(c)** The medical record must contain information to justify admission and continued hospitalization, supports the diagnosis, and describe the patient's progress and response to medications and services.
- 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.
- A0231 **CFR 482.24(c)(1)(i)** The author of each entry must be identified and must authenticate his or her entry.
- A0232 **CFR 482.24(c)(1)(ii)** Authentication may include signatures, written initials or computer entry.
- 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.
- 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.
- A0248 **CFR 482.25(a)** The pharmacy or drug storage area must be administered in accordance with accepted professional principles.
- A0250 **CFR 482.25(a)(2)** The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.
- A0251 **CFR 482.25(a)(3)** Current and accurate records must be kept of the receipt and distribution of all scheduled drugs.
- A0252 **CFR 482.25(b)** In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.
- A0254 **CFR 482.25(b)(2)** Drugs and biologicals must be kept in a locked storage area.
- A0255 **CFR 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

A0258 **CFR 482.25(b)(6)** Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

A0261 **CFR 482.25(b)(9)** A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

A0285 **CFR 482.27(b)** The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets the requirements of part 493 of this chapter.

A0290 **CFR 482.27(c)(1)** Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) Services furnished by an outside blood bank. If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

- (i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and
- (ii) The results of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and look back procedures are set forth at 21 CFR §610.45-et seq.)

(3) Quarantine of blood and blood products pending completion of testing. If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

- (i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.
- (ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR §606.40 and notify all patients in accordance with paragraph (c)(4) of this section.

(4) Patient notification. If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

- (i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.
- (ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.
- (iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.
- (iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) Timeframe for notification. The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless--

- (i) The patient is located and notified; or
- (ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) Content of notification. The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

- (i) A basic explanation of the need for HIV testing and counseling.
- (ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.
- (iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restriction the program may impose.

(7) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

A0296 **CFR 482.28(a)** The hospital must ensure that specific food and dietetic services organization requirements are met.

A0297 **CFR 482.28(a)(1)** The hospital must have a full-time employee who serves as director of the food and dietetic services; is responsible for daily management of the dietary services; and is qualified by experience or training.

A0317 **CFR 482.41** The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

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.

A0321 **CFR 482.41(b)** The hospital must ensure that specific life safety from fire requirements are met.

A0322 **CFR 482.41(b)(1)(2)(3)** Except as otherwise provided in this section, the hospital must meet the applicable provisions of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

[http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations;ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations;ibr_locations.html)

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to hospitals.

After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

A0326           **CFR 482.41(b)(6)** The hospital must have procedures for the proper routine storage and prompt disposal of trash.

A0331           **CFR 482.41(c)(2)** Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

A0338           **CFR 482.42** The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

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.

A0341           **CFR 482.42(a)(2)** The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

A0342           **CFR 482.42(b)** The chief executive officer, the medical staff, and the director of nursing must ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and be responsible for the implementation of successful corrective action plans in affected problem areas.

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.

A0390           **CFR 482.51(b)** Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

A0391           **CFR 482.51(b)(1)** There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the



patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

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.

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

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

A0404 CFR 489.20(r)(2) – 489.24(j)(1-2)

489.20(r)(2) The hospital (including both the transferring and receiving hospitals), must maintain a list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition.

489.24(j)(1) Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

489.24(j)(2)(i) The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.

489.24(j)(2)(ii) The hospital must have written policies and procedures in place to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

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.

A0418 **CFR 482.52(b)** Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities.

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.

A0447 **CFR 482.54(a)** Outpatient services must be appropriately organized and integrated with inpatient services.

A0448 **CFR 482.54(b)** The hospital must assign an individual to be responsible for outpatient services; and have appropriate professional and nonprofessional personnel available.

A0459 **CFR 482.55(b)(2)** There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

A0466 **CFR 482.56(a)(2)** Physical therapy, occupational therapy, or speech therapy or audiology services, if provided, must be provided by staff that meets the qualifications specified by the medical staff, consistent with State law.

A0467 **CFR 482.56(b)** Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

### **Federal Certification Critical Access Hospitals:**

C0190 **CFR 485.616** Agreements

C0191 **CFR 485.616(a)** In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network.

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.

C0203 **CFR 485.618(b)(1)** The items available must include drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

C0206 **CFR 485.618(c)(2)** The facility provides, either directly or under arrangements, blood storage facilities that meet the requirements of 42 CFR Part 493, Subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services

are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

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.

C0240 **CFR 485.627** Organizational structure

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

C0257 **CFR 485.631(b)(1)(i)** The doctor of medicine or osteopathy provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff.

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.

C0263 **CFR 485.631(c)(1)(i)** 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.

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.

C0276 **CFR 485.635(a)(3)(iv)** The policies include rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use. This regulation commonly cited when outdated drugs are not separated from those available for administration to patients, not keeping accurate records for scheduled drugs, and allowing unauthorized personnel access to pharmacy.

C0279 **CFR 485.635(a)(3)(vii)** The policies include, if the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §485.25(i) is met with respect to inpatients receiving post-hospital SNF care.

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

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.

C0293 **CFR 485.635(c)(4)(ii)** The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

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

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

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

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

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.

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.

C0335 **CFR 485.641(a)(2)** The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

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

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.

C0347 **CFR 485.643(c)** The CAH must have and implement written protocols that ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.

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.

C0365 **CFR 485.645(d)(1)** The resident has the right to be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being.

C0367 **CFR 485.645(d)(1)** The resident has the right to personal privacy and confidentiality for 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 a 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.

C0370 **CFR 485.645(d)(1)** The resident has the right and the facility must provide immediate access to any resident by any representative of the Secretary; subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and, subject to reasonable

restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

C0382 **CFR 485.645(d)(3)** The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

C0383 **CFR 485.645(d)(3)** The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. The facility must not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion.

C0384 **CFR 485.645(d)(3)** The facility must not employ individuals who have been found guilty of abusing, neglecting, or mistreating residents by a court of law; have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities. The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident and if the alleged violation is verified, appropriate corrective action must be taken.

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.

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

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

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

C0397 **CFR 485.645(d)(6)** The services provided or arranged by the facility must meet professional standards of quality.

C0402 **CFR 485.645(d)(7)** If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must--  
(1) Provide the required services; or  
(2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

### **State and Federal Certification for Ambulatory Surgical Centers:**

S0110 **KAR 28-34-52a(a)(1)** At a minimum, each facility shall ensure that each patient has a right to the following: (1) Receive respectful care given from competent personnel;

S0115 **KAR 28-34-52a(a)(2)** At a minimum, each facility shall ensure that each patient has a right to the following: (2) receive information of the proposed treatment or procedures to be performed, potential complications, and expected outcomes;

S0130 **KAR 28-34-52a(a)(5)** At a minimum, each facility shall ensure that each patient has a right to the following: (5) maintain privacy and security of self and belongings during the delivery of patient care service;

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

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

S0155 **KAR 28-34-52a(d)(1)** Each administrator of an ambulatory surgical center shall be responsible for reporting any incidents of abuse, neglect, or exploitation of any patient, in accordance with K.S.A. 39-1401 et seq., and amendments thereto.

S0160 **KAR 28-34-52a(a)(d)(2)** Each administrator of an ambulatory surgical center shall be responsible for reporting any incidents of abuse or neglect of children in accordance with K.S.A. 38-1521 et seq., and amendments thereto.

S0260 **KAR 28-34-53(e)** The governing authority shall be responsible for the implementation of a risk management program, in accordance with K.S.A. 65-4921 et seq. and amendments thereto, and K.A.R. 28-52-1 through 28-52-4.

S0330 **KAR 28-34-54(k)** The medical staff shall participate in risk management activities, in accordance with K.S.A. 65-4921 et seq., and amendments thereto, and K.A.R. 28-52-1 through 28-52-4,

and with the ambulatory surgical center's risk management plan. Any ambulatory surgical center having a medical staff with fewer than two physician members shall include provisions for outside peer review in the risk management plan.

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.

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.

R0805 **KAR 28-52-1. (e) (2)** Section II - a description of the measures used by the facility to minimize the occurrence of reportable incidents and the resulting injuries within the facility.

Regulation commonly cited when the facility fails to utilize the trending of incidents to minimize occurrences and improve facility processes. i. e. Providers with multiple occurrences are not identified for trending to minimize occurrences by those apparently high risk individuals.

R0806 **KAR 28-52-1(e)(3)** Plan format. Each submitted plan shall include the following:

Section III - a description of the facility's implementation of a reporting system based upon the duty of all health care providers staffing the facility and all agents and employees of the facility directly involved in the delivery of health care services to report reportable incidents to the chief of medical staff, chief administrative officer, or risk manager of the facility;

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

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

- A) Name and address of the facility;
- B) name and title of the facility's risk manager;

R0808 **KAR 28-52-1(e)(4)(C)** Plan format. Each submitted plan shall include the following:

Section IV C) description of involvement and organizational structure of medical staff as related to risk management program, including names and titles of medical staff members involved in investigation and review of reportable incidents;



R0809 **KAR 28-52-1(e)(4)(D)** Plan format. Each submitted plan shall include the following:

Section IV D) organizational chart indicating position of the facility's review committee as defined in K.S.A. 65-65-4923 and L. 1986, Ch. 229, new Section 4(a)(2);

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.

R0816 **KSA 65-4921(f)** Definitions. As used in K.S.A. 65-4930, and amendments thereto:

(f) "Reportable incident" means an act by a health care provider which:

- (1) is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or
- (2) may be grounds for disciplinary action by the appropriate licensing agency.

Regulation often cited because the incident was reported to the appropriate person, but not investigated by a duly constituted risk management committee, and/or closed record review findings of a possible reportable incident was not reported and/or not investigated.

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.

R0822 **KSA 65-4925(a)** The reports and records made pursuant to KSA 1986 Supp. 65-4923 or 65-4924, and amendments, thereto, shall be confidential and privileged, including:

- (1) Reports and records of executive or review committees of medical care facilities or of a professional society or organization;
- (2) reports and records of the chief of the medical staff, chief administrative officer or risk manager of a medical care facility;
- (3) reports and records of any state licensing agency or impaired provider committee of a professional society or organization; and
- (4) reports made pursuant to this act to or by a medical care facility risk manager, and committee, the board of directors, administrative officer or any consultant. Such reports and records shall not be subject to discovery, subpoena or other means of legal compulsion for their release to any person or entity and shall not be admissible in any civil or administrative action other than a disciplinary proceeding by the appropriate state-licensing agency.

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.

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

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

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

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

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