Kansas Department of Health and Environment
Bureau of Child Care and Health Facilities
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Annual Risk Management Report for 2004

"Effective Risk Management"

Is your risk management program proactive or reactive? Is your risk management program actively identifying areas of concern and potential areas of concern? Is your risk management program changing/adapting to meet the ever-changing challenges in the provision of healthcare?

The April 2005 AARP (American Association of Retired Persons) Bulletin quoted information from the American Association of Critical Care Nurses and Vital Smarts. According to that source 84% of physicians have observed co-workers take shortcuts that could be dangerous to patients. However, less than 10% reported what they saw!

JCAHO (Joint Commission on Accreditation of Healthcare Organizations) in July 2004 mandated a universal checklist before surgeries to identify the right patient, the right procedure and the correct surgery site for all facilities accredited by Joint Commission. In August 2004, JCAHO identified wrong site, wrong procedure or wrong patient surgeries as the third most reported sentinel event and held a conference to delve into application of the Universal Protocol.

In November 2004, NASHP (National Academy for State Health Policy) proclaimed State Patient Safety Centers as a new approach to promote patient safety. For the past five years, six states (FL, MD, MA, NY, OR, and PA) enacted legislation supporting the creation of state patient safety centers to help address the problem of medical errors. NASHP examined the various state models. To help patient safety advocates design safety centers that have the goal of reducing medical errors, NASHP recommended:

-Clear authority
-Coordinated activities
-Begin by focusing on creating a culture of safety

In September 2004, CMS (Centers for Medicare and Medicaid Services) and JCAHO made a joint announcement. They announced that hospital Quality Measures included heart attack, heart failure, pneumonia, and surgical infection prevention.

Infection control is an on-going challenge. The February 2003 Reader's Digest article, "Dirty Bed," written by Michael J Berens for The Chicago Tribune indicated that dirty hospitals kill 75,000 patients a year, unnecessarily. These preventable infections resulted from unsanitary facilities, germ-laden instruments, unwashed hands and other lapses. The article indicated that there is little incentive, and often little time, for doctors and nurses to comply with even basic standards. Nurses complained that just to wash between every patient contact could number up to 150 times daily, or about two and a half hours of time. Although many hospitals use waterless disinfectant, many staff members failed to adopt even this simple measure. The article noted that reportedly 50% of the doctors and nurses in hospitals do not clean their hands between patients.

KDHE (Kansas Department of Health and Environment) surveyors often cite infection control related citations during surveys. These citations related to the unsanitary conditions in the surgery suites, dietary departments, pharmacies, and other areas impacting patient care. On March 29, 2005, KDHE posted a report from the CDC (Centers for Disease Control) announcing cases of S (Serratia) Marcescens bloodstream infections related to intravenous Magnesium Sulfate infusion. CDC was most interested in S Marcescens infections occurring within 72 hours of the infusion, regardless of the manufacturer.

The March 2005 RN magazine article, "VAP Prevention, the latest guidelines," described the frequent complication of VAP (Ventilator-Associated Pneumonia) for patients on mechanical ventilation for 48 hours or more. This complication can prolong the patient's stay in Intensive Care for an average of 4.3 days. The additional treatment cost is $20,000 – 30,000. Up to one third of the patients who develop VAP die. A key to prevention is prevention of cross contamination, by appropriately gloving and gowning and washing hands with soap and water or alcohol-based antiseptic hand rub before and after contact. As noted above, reportedly 50% of the doctors and nurses in hospital do not clean their hands between patients. Nosocomial infections continue to be a concern.

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. Another area of non-compliance is investigating "near misses" through risk management. Although the error was caught, something happened or did not happen that should have and near miss 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. Next time, neither the patient nor you may be as fortunate.

Since the Institute of Medicine's research project on medical errors in 1999, many more states are joining the movement in developing mandated risk management programs through a state legislative process. In 2001, the Kansas Risk Management Specialist participated with other states and the National Academy for State Health Policy (NASHP) in the development of a guide for state executive and legislative branch officials for identifying and/or refining their policy goals for reporting systems. Each section of this guide, How Safe is Your Health Care? Building Accountability and Quality Improvement through State-Based Mandatory Reporting Systems, includes a narrative describing a key issue or concern, examples from existing systems, and a worksheet for states to complete as they build or adapt their system. The following categories are outlined in this report:

- How does a state identify its goals for mandatory reporting systems?
- What information will a state collect?
- Who will collect the information and administer the system?
- How will reports be submitted?
- How will information be stored?
- How will a state assure data accuracy?
- How will a state act on an incident report?
- What types of disclosure policies will be in place?
- How can a state learn from the information to enhance and/or sustain quality improvement?

While Kansas has accomplished most of these steps, the last step continues to be one that is most difficult to accomplish. One of the recommendations for completing the last step is that states establish a coalition for the prevention of medical errors to determine approaches for alerting and informing facilities about the risk of errors and 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. Some states have also invited consumers to participate with the coalition. At this time, Kansas does not have this type of organized coalition and there is not a system in place for the separate entities to share and review aggregated data collected and to assess for system improvement. However, members from the KARQM (Kansas Association of Quality and Risk Managers) and the KHA (Kansas Hospital Association) has been meeting with the KDHE in order to improve communication between these organizations/agencies in regard to the risk management process. Hopefully, this will lead to the organization of a coalition that can learn from the information gathered by all of the stakeholders 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. In

May of 2000, KDHE began a new quarterly report form included a section for medical facilities to document systematic changes they have implemented to improve patient care and minimize the occurrences of medical errors. Approximately 35% of the hospitals completed this part of the quarterly report during 2004.

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 have had wrong eye cataract surgery completed even after all the publicity and recommendations. 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. We must find a better way to communicate potential problem areas and encourage medical care facilities to implement safer practices.

Three studies were completed in Colorado, Utah and New York to determine the number of deaths caused by adverse events. These studies found that adverse events occurred in 2.9 to 3.7 percent of hospitalizations. In Colorado and Utah, 8.8% of these adverse events led to death, as compared to 13.6 percent in New York hospitals. Kansas medical care facilities reported 89,306 adverse events in 2004.

It must be understood that the definition for an adverse event is not universal. 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 47 occurrences that must be reported follows the definition.

In Kansas, a reportable adverse event would include all unexpected occurrences in which the standard of care was not met and that injury occurred or there was a probability of injury. This would include minor injuries as well as the more severe. Kansas adverse events also include those incidents that were possible grounds for disciplinary action by the appropriate licensing agency, such as, unprofessional conduct. Many of the adverse events reported in Kansas, would not be reported to these other entities, therefore it is impossible to accurately compare the data with other states.

Brief History of Kansas Risk Management

This report represents the nineteenth in a series written by KDHE staff. The report outlines the issues, problems, findings, and significant changes which have occurred in the implementation of the Kansas Risk Management law (KSA 65-4921 et. Seq.).

In 1987, House Bill 2661 passed requiring every medical care facility in Kansas to establish an internal risk management program. On September 1, 1987, Bill Rein was named as the Director of Quality Assurance and Risk Management to provide oversight for the new legislative mandate. In 1988, risk management surveys began with annual surveys of 160 facilities by two Risk Management Specialists.

In 1996 following passage of House Bill 2867, combination licensure and risk management surveys for all non-accredited hospitals and ASCs (Ambulatory Surgical Centers) were initiated to assure compliance. Two Risk Management Specialists surveyed the 187 facilities at least every three years. The 1997 article, entitled "The Kansas Risk Management Program: What Has Changed and What Remains the Same", explored the changes and early implementation efforts brought on by passage of House Bill 2867. That article explained the conceptual process of incorporating risk management laws and statutes with existing state licensure regulations into a revised "standards review" which had not been conducted in a number of years. A limitation on similar Medicare surveys was a result of revised federal funding priorities. The article presented the philosophy and development of a new survey instrument, a summary of the types and frequency of deficiencies cited during the initial reviews, as well as statistics historically gathered on risk management reporting to licensing agencies.

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

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

“To Error is Human, BUT can be Deadly” submitted in 2001, reviewed the risk management program for calendar year 2000. There is 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 the KARQM and the 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.

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 which were approved in April 2001. The CMS (Centers for Medicare and Medicaid Services) 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, 2004, there were fifty-three ASCs. Three of the four 2004 ASC surveys were initial surveys.

Acute Care and Critical Access Hospitals

Implementation of the new combined licensure/survey process for medical care facilities began on December 1, 1996. The goal was to survey each hospital at least every two and a half to three years.

In 2000, federal certification requirements for resurveys in non-accredited hospitals were increased from 5% to 33% each year. Since many of the regulations are similar, the federal certification resurvey and licensure/risk management processes were combined to meet the increased workload.

Along with the increase of federal certification requirements, Kansas has had an increase in the number of hospitals converting to CAH (Critical Access Hospitals). There were 19 initial surveys completed in 2001 with 13 of those 19 changing from an acute care hospital to a CAH. Kansas continues to lead the states in the number of CAHs. As of December 31. 2004, there were 74 Critical Access Hospitals in Kansas. Each time an acute care hospital converts to a CAH, it requires an initial survey of that facility using the federal CAH regulations. Approximately one year after the initial CAH survey is completed, KDHE should return to the facility for a certification and risk management resurvey. Thereafter, the CAH is placed on the rotation to be surveyed approximately every three years. Either with the initial CAH survey or the survey occurring approximately one year after the initial survey, KDHE surveys the facility to assure compliance with Risk Management regulations. Converting to a CAH has not demonstrated any changes in the risk management outcomes. It is hopeful that the supporting hospitals will be able to assist the CAHs with improving their risk management and quality improvement programs which may lead to improvement in patient safety. During 2004, surveyors completed six initial CAH surveys.

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.

The 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 three years between surveys. New risk managers and some experienced risk managers do not understand the necessity of protecting the reporter's name, assuring that risk management information is secured at all times, or the necessity of take immediate action when an error occurs. These risk managers do not understand the requirement to further minimizing occurrences by tracking "near misses" or to find ways to improve processes. 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 the individual case. 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 have seen 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. 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. 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

In addition to conducting on-site surveys, the KDHE's Risk Management Specialist has been involved in other risk management activities. Those activities included, but were not limited to:

1) review and approval of new and amended risk management plans;
2) respond to inquiries about state and federal regulations and the risk management process;
3) review adverse events and their corrective action as reported by facilities;
4) review facilities' quarterly reports;
5) advise new facility applicants of risk management requirements;
6) provide consultation and presenting workshops and training to risk managers and hospital personnel throughout the state; and
7) provide consultation and training to KDHE surveyors.

The turnover of risk managers throughout the state continues and many are placed in their positions without training or orientation. In 2004, the Risk Management Specialist provided educational programs for medical care facilities throughout the state, both in a group settings and on an individual basis. The group educational sessions presented by the Risk Management Specialist included: Risk Management101, Infection Control, and Risk Management in today's world.

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 should receive a revisit within six months. The date of a revisit will depend on the anticipated date of correction that the facility has placed on their Statement of Deficiencies and Plan of Correction (2567) but no later than six months after the original standard survey. The survey revisit is 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 interview, 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 code/tag. Each regulation is divided into several codes/tags.

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.

CAHs were surveyed for compliance with certification and risk management regulations. 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. Both hospitals with swing beds and CAHs have experienced the following problems found during the survey process:

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

Risk Management Goals for 2005

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 on the

Risk Management/Licensure and Certification

Survey Process

Glossary of Terms

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Appendixes

Frequently Cited Tags

Glossary of Terms

ASC.....Ambulatory Surgical Center
BCCHF.....Bureau of Child Care and Health Facilities
CFR.....Code of Federal Regulations
CAH.....Critical Access Hospital
KAR.....Kansas Administrative Regulations
KARQM.....Kansas Association of Quality and Risk Managers
KDHE.....Kansas Department of Health and Environment
KHA.....Kansas Hospital Association
KSA.....Kansas Statutes Annotated
KSBHA.....Kansas State Board of Healing Arts
KSBN.....Kansas State Board of Nursing
KSPB.....Kansas State Pharmacy Board
MDS.....Minimum Data Set
SB MDS.....Swing Bed Minimum Data Set
SOC.....Standard of Care
TAGS.....(Survey Reference) Tags

Tables Introduction

Historically data has been presented to medical care facilities related to the number of incidents confirmed to meet standard of care determination levels 3 or 4, the agency to which the incident was reported, and the number of reports generated by facility size. These figures are updated through the end of 2004 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 Standard of Care (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 - 2003

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%)

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

**The 2002 total number of incidents by all providers was 93,627 with 501 SOC IIIs and SOC IVs or 5.35% .

***The 2003 total number of incidents by all providers was 87,359 with 572 SOC IIIs and SOC IVs or 6.55%, an increase.

****The 2004 total number of incidents by all providers was 89,306 with 519 SOC IIIs and SOC IVs or 5.81%, a decline.

Table 2

Comparison of Total Number of **Reportable Incidents** Generated
By Facility Size and Licensing Agency
1996-2004

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

Table 2 Continued						
101-200 beds	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
	2004	18 or 17%	65 or 60%	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	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	2004	2 or 29%	3 or 43%	2 or 29%	0	0
	2003	0	0	0	0	0
	2002	1 or 8%	0	3 or 23%	0	9 or 69%
	2001	`0	0	0	0	0
	2000	2 or 40%	0	0	0	3 or 60%
	1999	0	0	1 or 100%	0	0
	1998	0	0	0	0	0
	1997	0	2 or 100%	0	0	0
	1996	3 or 42%	0	2 or 29%	0	2or 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, 2001, 2003, and 2004

Facilities by by Size Category	Number of Facilities in Size Category	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
1 - 25 beds	82 facilities	218/97	213/97	238/140	264.3/127
26 - 50 beds	19 facilities	373/102	362/71	385/75	413.8/51
51 - 100 beds	26 facilities	591/86	485/38	568/88	606/45
101 - 200 beds	13 facilities	906/7	780/55	1097/60	1009/108
200 + beds	14 facilities	2093/242	2057/191	2803/201	208.9/179
ASCs	55 facilities	24/5	28.5/0	33.7/0	29.8/9
Totals	209 facilities	/571	/436	436.8/564	427/519

*__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 75,0000 patients a year, unnecessarily. The article noted 50% of the doctors and nurses in hospitals do not clean their hands between patients. The article was written in 2003.

17. **“Higher toll cited from hospital errors”** by Scott Allen, Globe staff. The article-identified medical mistakes as the third-leading cause of death in the United States, behind heart disease and cancer. The article quoted Dr Samantha Collier, vice president of medical affairs at HealthGrades, which publishes rankings of hospitals and doctors. This article was written in 2004.

18. **“VAP Prevention, the latest guidelines,”** describes this type of pneumonia as a frequent complication fro 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.

APPENDIX A

Total of Survey Codes Cited During
Acute Care Hospital Licensure/Certification Surveys
2004

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
H0042	1	A0110	1	A0251	2	A0402	1
H0044	2	A0122	1	A0253	1	A0404	1
H0114	1	A0167	1	A0254	1	A0362	2
		A0184	2	A0255	1	A0405	3/1*
A0012	2	A0185	1	A0258	1	A0406	1
A0013	2	A0188	1	A0270	1	A0407	1
A0015	1	A0201	1	A0271	1	A0408	1
A0028	1	A0204	3	A0275	1	A0421	1
A0040	1	A0205	2	A0290	2	A0467	1
A0041	1	A0208	2	A0302	1	A0752	1
A0044	2	A0227	1/1*	A0307	1	A0753	1
A0045	2	A0231	1	A0318	6	A0757	2
A0046	5	A0235	1	A0329	1	A0761	1
A0047	1	A0236	1	A0331	2	A0762	1
A0049	1	A0238	1	A0340	6	A0764	1
A0055	1	A0239	1	A0341	1	A0765	1
A0057	1	A0240	1	A0350	1	A0766	2
A0058	1	A0241	3	A0352	1	A0772	2
A0059	2	A0243	1	A0354	1	A0777	1
A0060	3	A0245	2	A0356	1	A1533	1
A0083	2	A0246	1	A0357	1	A1534	1
A0084	2	A0247	1	A0360	1	A1537	1
A0100	1	A0248	1/2*	A0364	1		
A0102	1	A0249	1	A0389	1		

*Regulations revised with content change at reference tags. See Appendix I

APPENDIX B

Total of Survey Codes Cited During
Critical Access Hospital Certification Surveys
2004

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
C0195	1	C0278	1	C0361	1
C0204	2	C0279	1	C0362	1
C0222	2	C0302	1	C0364	1
C0223	1	C0304	1	C0368	1
C0224	1	C0307	2	C0369	1
C0225	3	C0308	2	C0370	1
C0241	1	C0321	1	C0371	1
C0258	1	C0322	1	C0372	1
C0263	1	C0331	1	C0384	2
C0271	2	C0332	1	C0385	2
C0272	2	C0333	1	C0388	1
C0276	2	C0334	1	C0395	1
C0277	1	C0337	2	C0397	1

APPENDIX C

Total of Survey Codes Cited During
Ambulatory Surgical Center Licensure and Certification Surveys
2004

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
Q0002	1	S0155	1
Q0020	1	S0160	1
		S0375	1
		S0845	1

APPENDIX D

Total of Survey Codes cited During
Hospital, CAH and ASC **Risk Management** Surveys
2004

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
R0800	3	R0820	1	R0829	3
R0801	4	R0822	1	R0830	1
R0802	5	R0824	1	R0831	1
R0805	1	R0825	4	R0832	6
R0806	1	R0826	2	R0833	9
R0808	1	R0827	1	R0837	3
R0816	1	R0828	2		

APPENDIX E

Most Frequently Cited Survey Codes and Percentage of
Facilities Cited During **7 Hospital** Certification & Licensure
2004

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
A0318 - Buildings	6	86%
A0340 – Organization and Policies	6	86%
A0046 – Notice of Rights	5	71%
A0060 – Confidentiality	3	43%
A0204 – Staffing and Delivery of Care	3	43%
A0241 – Content of Record	3	43%
A0405 – Central Log	3	43%

APPENDIX F

Most Frequently Cited Survey Codes and Percentage of
Facilities Cited During **9 CAH Hospital** Certification Surveys
2004

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
C0225 - Maintenance	3	33%
C0204 – Equipment and Supplies	2	22%
C0272 – Patient Care Policies	2	22%
C0307 – Record System	2	22%
C0308 – Protection of Record Information	2	22%
C0385 – Quality of Life	2	22%
C0337 – Quality Assurance	2	22%

APPENDIX G

Most Frequently Cited Survey Codes and Percentage of
Facilities Cited During **16 Hospital & CAH** Risk Management Surveys
2004

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
R0833 – Separate SOC per provider and clinical issue	8	50%
R0832 – Appropriate SOC determination	6	37%
R0802 – Findings, conclusions, recommendations, actions taken, and results documented and reported through procedures established with RM plan.	5	31%
R0801 – Plan approved and reviewed annually the governing body	4	25%
R0825 – Written acknowledgement of incident report receipt.	4	25%

APPENDIX H

Most Frequently Cited Survey Codes and Percentage of
Facilities Cited During **4 ASC** Certification & Licensure/Risk Management Surveys
2004

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
Q0002 – Compliance with State Licensure	1	25%
Q0020 – Membership and Clinical Privileges	1	25%
S0155 – Patient Rights	1	25%
S0160 – Patient Rights	1	25%
S0375 – Human Resources	1	25%
S0845 – Physical Environment	1	25%
R0801 – Plan approved and reviewed annually by the governing body	1	25%
R0822 – Reports, records and proceedings confidential and privileged	1	25%
R0826 – Written acknowledgement of incident report receipt	1	25%
R0833 – Separate SOC per provider and clinical issue	1	25%

APPENDIX I

2004 Cited Survey Codes

State Licensure and Federal Certification Acute Care Hospital:

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.

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.

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.

A0013 **CFR 482.12 (a)(6)** The governing body must ensure that criteria for selection are individual character, competence, training, experience, and judgment.

A0015 **CFR 482.12(b)** The governing body must appoint a chief executive officer is responsible for managing the hospital.

Commonly this deficiency is citied when the hospital has care issues, and the chief executive officer is not involved in corrective action and/or knowledgeable of the issues.

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.

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.

A0041 **CFR 482.13(a)(2)** The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

A0044 **CFR 482.13(a)(2)(i)** The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

A0045 **CFR 482.13(a)(2)(ii)** The grievance process must specify time frames for review of the grievance and the provision of a response. .

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.

A0047 **CFR 482.13(b)** The patient has the right to participate in the development and implementation of his or her plan of care.

A0049 **CFR 482.13(b)(2)** The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.

A0055 **CFR 482.13(c)** 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.

A0083 **CFR 482.13(f)(3)(ii)(D)** Each written order for physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9.

A0084 **CFR 482.13(f)(3)(ii)(D)** The original order may only be renewed in accordance with these limits for up to a total of 24 hours

A0100 **CFR 482.24(b)** The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas

A0102 **CFR 482.24(c)** 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.

A0110 **CFR 482.24(c)** All records must document, as appropriate, 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.

A0122 **CFR 482.25(b)** Drugs and biologicals must be kept in a locked storage area. Drugs and biologicals are often found in unsecured, attended areas, especially radiology. Cleaning supplies are left unsecured in unlocked cabinets and rooms and on unattended cleaning carts.

(Found at A0254 in subsequent regulation version.)

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.

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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 482.2(a)** There must be administrative and technical personnel competent in their respective duties.

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.

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.

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.

A0227 **CFR 482.24(b)(3)** The hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.

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.

A0231 **CFR 482.24(c)(1)(i)** The author of each entry must be identified and must authenticate his or her entry.

A0235 **CFR 482.41(b)** The hospital must have procedures for the proper routine storage and prompt disposal of trash.

A0236 **CFR 482.24(c)(2)(iii)** All records must document results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

A0238 **CFR 482.24(c)(2)(v)** All records must include properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

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

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

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

A0243 **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.

A0245 **CFR 482.42(a)** The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

A0246 **CFR 482.42(a)** The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

A0247 **CFR 482.42(b)** The chief executive officer, the medical staff, and the director of nursing services must meet their responsibilities in regard to infection control issues.

A0248 **CFR 482.15(a)** The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

CFR 482.42(b) The chief executive officer, the medical staff, and the director of nursing services must ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers.

A0249 **CFR 482.42(b)** The chief executive officer, the medical staff, and the director of nursing services must be responsible for the implementation of successful corrective action plans in affected problem areas.

A0251 **CFR 482.25(a)(3)** Current and accurate records must be kept of the receipt and distribution of all scheduled drugs.

A0253 **CFR 482.25(b)(1)** All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

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

(Found at A0122 in a previous version.)

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.

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

A0271 **CFR 482.26(b)(2)** Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

A0275 **CFR 482.26(c)(1)** A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiological tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

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.

A0302 **CFR 482.28(b)** Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

A0307 **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.

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.

A0329 **CFR 482.41(c)** The hospital must maintain adequate facilities for its services.

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

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.

A0350 **CFR 482.43(a)** The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

A0352 **CFR 482.43(b)(2)** A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

A0354 **CFR 482.43(b)(4)** The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

A0356 **CFR 482.43(b)(6)** The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

A0357 **CFR 482.43(c)** The hospital must ensure that specific discharge plan requirements are met.

A0360 **CFR 482.43(c)(3)** The hospital must arrange for the initial implementation of the patient's discharge plan.

A0362 **CFR 482.43(c)(5)** As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

A0364 **CFR 482.43(e)** The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

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.

A0402 **CFR 489.20(q)** In the case of a hospital as defined in W489.24(b)--

(1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and

(2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under Title XIX;

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.

A0405 **CFR 489.20(r)(3)** A central log on each individual who comes to the emergency department, as defined in W489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

(Regulation tag number remains unchanged in subsequent version.)

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.

A0408 **CFR 489.24(c)(3)** A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (c) in order to inquire about the individual's method of payment or insurance status.

Often the medical screening examination is <u>not</u> just delayed, it is never completed.

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.

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.

A0752 **CFR 482.13(a)(1)** A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

A0753 **CFR 482.13(a)(2)** The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

A0757 **CFR 482.13(a)(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.

A0761 **CFR 482.13(b)(3)** The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with 489.100 of this part (Definition), 489.102 of this part (Requirements for providers), and 489.104 of this part (Effective dates).

A0762 **CFR 482.13(b)(4)** The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

A0764 **CFR 482.13(2)** The patient has the right to receive care in a safe setting.

A0765 **CFR 482.13(3)** The patient has the right to be free from all forms of abuse or harassment.

A0766 **CFR 482.13(d)** The patient has the right to the confidentiality of his or her clinical records.

A0772 **CFR 482.13(e)(3)(ii)(A)** An order for restraint, must never be written as a standing or on an as needed basis (that is, PRN).

A0777 **CFR 482.13(e)(4)** An order for restraint must be ended at the earliest possible time.

A1533 **CFR 482.66(b)(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.

A1534 **CFR 482.66(b)(3)** The facility must not employ individuals who have been—
Found guilty of abusing, neglecting, or mistreating residents by a court of law; or
(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and
(iii) 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.
2) 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).

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

(4) 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.

A1537 **CFR 482.66(b)(4)** The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

The activities program must be directed by a qualified professional who—
Is a qualified therapeutic recreation specialist or an activities professional who—
Is licensed or registered, if applicable, by the State in which practicing; and
(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.

Federal Certification Critical Access Hospitals:

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.

C0204 **CFR 485.618(b)(2)** The items available must include equipment and supplies commonly used in life saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

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

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

C0224 **CFR 485.623(b)(3)** Drugs and biologicals are appropriately stored. There continues to be a problem with facilities not securing drugs and cleaning supplies. The cleaning supplies are labeled as dangerous if swallowed and is a risk especially for children and confused adults.

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

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

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

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.

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

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

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.

C0302 **CFR 485.638(a)(2)** The records are legible, complete, accurately documented, readily accessible, and systematically organized.

C0304 **CFR 485.638(a)(4)(i)** For each patient receiving health care services, the CAH maintains a record that includes, as applicable, identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient.

C0307 **CFR 485.638(a)(4)(iv)** For each patient receiving health care services, the CAH maintains a record that includes, as applicable, dated signatures of the doctor of medicine or osteopathy or other health care professional.

C0308 **CFR 485.638(b)(1)** The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

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

C0321 **CFR 485.639(a)** The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by a doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; a doctor of dental surgery or dental medicine; or a doctor of podiatric medicine.

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

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.

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.

Regulation 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).

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.

C0362 **CFR 485.645(d)(1)** The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section.

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

C0368 **CFR 485.645(d)(1)** The resident has the right to refuse to perform services for the facility or perform services for the facility, if he or she chooses, when the facility has documented the need or desire for work in the plan of care; the plan specifies the nature of the services performed and whether the services are voluntary or paid; compensation for paid services is at or above prevailing rates; and the resident agrees to the work arrangement described in the plan of care.

C0369 **CFR 485.645(d)(1)** The resident has the right to privacy in written communications, including the right to send and promptly receive mail that is unopened; and have access to stationery, postage, and writing implements at the resident's own expense.

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

C0371 **CFR 485.645(d)(1)** The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights and safety of other residents.

C0372 **CFR 485.645(d)(1)** The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

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.

C0388 **CFR 485.645(d)(6)** The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

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

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

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

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

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

State and Federal Certification for Ambulatory Surgical Centers:

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.

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

S0845 **KAR 28-34-61a(d)(2)** Fire and disaster drills. Develop a written plan for addressing the safety of patients, staff, and visitors during disasters. Periodic drills shall be held, and a record of each drill shall be kept on file.

Regulation commonly cited when facility has a written fire and disaster plan but fails to provide drills to assure that all staff are knowledgeable concerning their responsibility during a fire or disaster.

Q0002 **CFR 416.40** The ambulatory surgical center must comply with state licensure requirements.

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

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.

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;

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;

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.

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.

R0824 **KAR 28-52-2(a)** Each medical care facility shall identify a written form on which employees and health care providers shall report clinical care concerns to the risk manager, chief of staff, or administrator.

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

R0826 **KAR 28-52-2(b)** The risk manager, chief of staff, or administrator shall acknowledge the receipt of each incident report in writing. This acknowledgment may be made in the following manner:
(1) file stamping each report;
(2)maintaining a chronological risk management reporting log;
(3) signing or initialing each report in a consistent fashion; or
(4) entering pertinent information into a computer database.

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

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

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

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

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

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

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

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

A837 **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.