



Kansas Department of Health and Environment
Bureau of Child Care and Health Facilities
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Annual Risk Management Report for 2010

“Effective Communication”

“As we men of medicine grow in learning we more justly appreciate our dependence on each other. The sum total of medical knowledge is now so great and wide spreading that it would be futile for any one man . . . to assume that he has even a working knowledge of any part of the whole . . . The best interest of the patient is the only interest to be considered, and in order that the sick may have the benefit of advancing knowledge, union of forces is necessary . . . It has become necessary to develop medicine as a cooperative science; the clinician, the specialist, and the laboratory workers uniting for the good of the patient, each assisting in elucidation [*clarification*] of the problem at hand, and each dependent upon the other for support.” This is a portion of Dr. William J Mayo’s oration to the 1910 graduating class of Rush Medical College. Even without substituting “women and men” for the term “men” in the quotation, Dr Mayo’s statement is just as relevant today as it was 100 years ago.

Dr Mayo repeatedly said that a sick person was not like a wagon, to be taken apart and repaired in pieces, but should be examined and treated as whole. For complex cases, effective communication continues to be vital, but difficult to achieve.

When DRGs (Diagnostic Related Groups) were initiated in hospitals in the mid-1980s to save the Medicare program from insolvency, reimbursement became one of the driving factors on type of care received, length of stay etc. Many healthcare insurers followed Medicare’s lead. Since hospitals were no longer being reimbursed in relationship to the actual cost of care and care based on the patient’s total needs, the focus was shifted to providing care for a specific condition(s) and containing cost, if possible, within the pre-determined reimbursement rate. For better or worse, patient stays were often significantly reduced. This reduction reduced patient related costs, reduced potential for a hospital acquired infection(s), but also shortened the window of opportunity to assess the patient as a whole, identify other significant problems, allow for involved healthcare personnel to communicate and formulate an effective care plan, and allow for accurate evaluation of intervention effectiveness.

Out of this shift to reimburse at a pre-set rate, more and more surgical procedures were completed on an outpatient basis through hospital same day surgery units and free standing ambulatory surgery centers. Prior to DRGs, patients commonly came to the hospital the night before. Now almost all patients report to the facility the day of the procedure and some pre-operative evaluations are conducted just prior to surgery. This practice requires healthcare personnel to complete their assessment(s) in a much shorter time frame. Communication between all involved healthcare personnel and the patient or patient representative is critical.

For conditions that used to warrant a several day stay in the hospital, patients stay overnight or receive treatment as an outpatient. In the 1950s, women commonly stayed in the hospital for ten days after delivering a baby. The physician and staff had ample time to identify and intervene when complications were identified. In the 1970s, the post-delivery stay was about three days. For a brief period of time in the 1980s, insurers treated childbirth as an outpatient procedure and did not reimburse for overnight stay unless complications arose. After deaths, near deaths, and other less significant complications for babes and/or new moms occurred within a few hours and days after delivery, insurers began reimbursing for an overnight stay. With shortened stays, effective communication became even more essential.

An example of vital communication is “time out” prior to surgery. The “Time Out” protocol is an opportunity for the surgical team to pause and identify, verify, and confirm that the surgical procedure that are planning to perform is the matches the informed consent, is the correct procedures, in the correct site, on the correct individual, by the correct surgeon. Although most facilities have adopted some form of a “time out” protocol, occasions still arise when protocols are not followed or not implemented appropriately. Unfortunately, patients continued to be subjected to wrong site surgery and procedures that were not intended for them.

Communication comes in many forms. The two most common are written and verbal. Technology has significantly expanded communication modes.

Healthcare facilities utilize electronic medical records or soon will. For many, the main focus when purchasing a system, in addition to cost, is user friendliness. While this is very important, it is just as important to be able to retrieve the information from the electronic medical record in a usable form. Retrieval has been more of a challenge, than user friendliness. Of course, the information must be entered into the medical record before it can be retrieved the information documented in the medical record must be meaningful. Failure to document has impeded communication and been an issue for healthcare as long as there has been documentation.

Transitions of Care (hand-off) information sharing should occur with change of shift, patient change of location, and collaboration. Sources for the information are involved staff, the patient, family, and anyone else with pertinent information. Many of these exchanges occur verbally. In some instances, there is no communication at all. They should contain necessary information related to care of the patient. Most of the problems identified in this arena occur when information is inaccurate or omitted either intentionally or accidentally.

In 2008 and 2009, the Kansas Risk Management Specialist participated on the Kansas Pressure Ulcer Collaborative and its sub-committee, Care Transition Team. In 2009, the Care Transition Team reviewed forms from countless facilities and conducted an on-line survey related to patient transfer, with healthcare personnel at all levels of care. Participants consistently identified core information that should be on the transfer form. These participants reported that although they consistently provide the needed information on transfer forms, they seldom received the necessary information when they receive a patient. Clear reasons for this discrepancy between knowing and consistently sharing and not receiving were not identified in the survey.

Effective in October 2009, Medicare stopped paying hospitals for avoidable errors. These errors include infections, wrong site surgery, serious pressure ulcers (stage III or IV), etc. Other healthcare insurers also no longer pay for expenses related to medical errors.

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

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

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

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

Members from KARQM (Kansas Association of Quality and Risk Managers) and KHA (Kansas Hospital Association) continue to meet with KDHE in order to improve communication between these entities in regard to the risk management process. Our goal is to continue an open dialogue so we may learn from each other and improve the quality of care in Kansas medical care facilities. Many aspects of patient safety and “just culture” are being considered for inclusion in the risk management regulations.

KDHE publishes an annual report with aggregate data collected from the risk management quarterly reports, but these results by themselves do not enhance quality improvement. Only the facility can develop and implement such systems. The quarterly report form includes a section for medical care facilities to document systematic changes they have implemented to improve patient care and minimize the occurrences of medical errors. Approximately 10 % of the facilities completed this part of the quarterly report during 2010.

The book To Err is Human, written by the Institute of Medicine in 1999, emphasized that the medical field will never be able to completely stop medical errors, as the staff that order, prepare and administer the care are human and humans do make mistakes. But it is very clear that if we improve the processes of ordering, preparing and administering care, these improvements will assist us “humans” from making some of these errors.

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

Because the definition for an adverse event is not universal it is impossible to compare data from state to state. The definition for adverse or a sentinel event from the Joint Commission on Accreditation of Healthcare Organization is “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.” Some states have adopted “never” events. Colorado’s definition is “All deaths arising from unexplained causes or under suspicious circumstances. Brain and spinal cord injuries. Life-threatening complications of anesthesia. Life-threatening transfusion errors or reactions. Burns; missing persons; physical, sexual, and verbal abuse; neglect; misappropriation of property; diverted drugs; malfunction or misuse of equipment.” New York’s definition is “An unintended adverse and undesirable development in an individual patient’s condition

occurring in a hospital.” A list of 36 occurrences (reduced from 47) that must be reported follows the definition. New York has had this mandatory reporting for more than 20 years, and many from that state voice frustration that they have not moved beyond data gathering to actual evaluation and corrective action to prevent reoccurrence.

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

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

Brief History of Kansas Risk Management

This report represents the twelfth 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, a Director of Quality Assurance and Risk Management was named to provide oversight for the new legislative mandate. In 1988, risk management surveys began with annual surveys of 160 facilities by two Risk Management Specialists.

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

The 1997 article, entitled “The Kansas Risk Management Program: What Has Changed and What Remains the Same,” explored the changes and early implementation efforts brought on by passage of House Bill 2867. That article explained the conceptual process of incorporating risk management laws and statutes with existing state licensure regulations into a revised “standards review” which had not been conducted in a number of years. A limitation on similar Medicare surveys was a result of revised federal funding priorities. The article presented the philosophy and development of a new survey instrument, a summary of the types and frequency of deficiencies cited during the initial reviews, as well as statistics historically gathered on risk management reporting to licensing agencies.

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

“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 for risk management issues and compliance.

“To Error is Human, BUT can be Deadly” (submitted in 2001 for 2000) reported 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. Emphasis was 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.

In 2001, the Director of Medical Facilities (now Health Facilities Program) and the Risk Management Specialist met with members of members of KARQM and KHA in order to improve communication between these organizations/agencies in regard to the risk management process. This group continues to meet on an ongoing basis to work on developing meaningful interpretations of these definitions. The goals of the meetings are to ensure a more universal reporting system for Kansas and to improve communication between associations and organizations that play a part in the risk management process. (Starting in 2009, the Risk Management Specialist met periodically with peers from other states during the National Quality Forum patient safety conferences with a goal to develop protocols to improve patient safety.)

“Reduction of Preventable Errors – A Mandate, Not an Option” (submitted for 2003) stressed the high toll from hospital errors. On July 28, 2004, the National Academy for State Health Policy released a bulletin entitled, “Higher toll cited from hospital errors,” by Scott Allen, Globe Staff. The article identified medical mistakes as the third-leading cause of death in the United States, behind heart disease and cancer. The article quoted Dr Samantha Collier, vice president of medical affairs at HealthGrades, which publishes rankings of hospitals and doctors. According to Dr Collier, “There is little evidence that patient safety has improved in the last five years.” “The equivalent of 390 jumbo jets full of people are dying each year due to likely preventable, in-hospital medical errors, making this one of the leading killers in the US.” Many hospitals now have “rescue” teams that are activated whenever a patient’s status changes or fails to improve. These teams are empowered to “take charge” of the patient’s care, if indicated.

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

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

“The Triumphs and Challenges of Emergency Medicine” (submitted for 2006) spot lighted emergency medicine’s progress and shortcomings. On 6/13/07 an Associated Press release entitled “Woman dies in

ER lobby as 911 refuses to help” stunned all who heard or read the release. The common questions were “What went wrong?” and “How could this happen?” We still don’t have all the answers, but many hospitals have taken corrective action, as a result of this death.

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

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

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

“First, Do No Harm – Preventing the Avoidable” (submitted for 2009) stressed putting the patient first and being proactive and nurturing to create the best environment for the delivery of the highest quality of care possible. In many hospitals, nurses are working with patients (nurturing) to help them adopt healthier life styles. Staff offer support to promote success, listen to the patient and significant others, and provide teaching and training at a level that the patient and their significant others can understand.

Risk is not totally eliminated in the best of environments, but potential for adverse events is reduced when everyone is working together proactively to prevent avoidable occurrences. We are seeing improvements and proactive prevention in many of our Kansas facilities.

Ambulatory Surgical Centers

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

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

Actions were taken by the Federal government that became effective in 2009. Kansas was one of the first twelve states to apply the new protocols in 2009. KDHE implemented a revised ASC certification and licensure survey process using the revised federal survey process. The new survey process increased survey time, required additional surveyor ASC training, and increased survey rates in 2010 to 33 percent.

In FY 2010, CMS mandated that the states:

- 1) complete ASC surveys for 33% of the state’s non-accredited ASCs each year for compliance with federal regulations;
- 2) complete ASC validation surveys for 5% of the state’s deemed ASCs each year; and

- 3) complete additional surveys to insure that no more than 6.0 years elapses between surveys of any one non-deemed ASC provider.

As medical care and reimbursement rates change and overnight stay 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, 2010, there were seventy ASCs.

Acute Care and Critical Access Hospitals

Since many of the regulations are similar, the federal certification resurvey and licensure processes are combined to meet the increased workload. In FY 2010, CMS mandated that the states:

- 1) complete targeted surveys each year for compliance with federal regulations and ensure that no more than five years elapses between surveys for any one particular non-accredited hospital or non-accredited CAH (critical access hospital) for not less than 5% of each of the two types of hospitals;
- 2) complete targeted surveys each year for compliance with federal regulations and ensure that at least 5% of the short-term, acute care, non-accredited hospitals/CAHs listed by CMS as facilities at high risk for providing poor care;
- 3) complete additional surveys to insure that no more than 4.5 years elapses between surveys of any one particular non-accredited hospital or non-accredited critical access hospital; and
- 4) ensure that all non-accredited hospital or non-accredited critical access hospital are surveyed at least every 3.0 years, on average.

As of December 31, 2010, Kansas had 73 licensed hospitals that were not designated as CAHs. Kansas continues to lead the states in the number of CAHs. As of December 31, 2010, there continued to be 83 Critical Access Hospitals in Kansas. Converting to a CAH has not demonstrated any changes in the risk management outcomes. Hopefully, the supporting hospitals will continue to assist the CAHs in developing proactive and effective risk management and quality improvement programs. The goal is for these developments to lead to an overall improvement in patient safety and quality of care.

Survey Activity

Each hospital should anticipate that the routine licensure and certification survey process takes approximately one week to complete. An ASC routine licensure and certification survey, depending on size, will take approximately three to four days, with incorporation of the revised federal survey process. When deficiencies are cited, the facility may receive a revisit within six months. A survey revisit, for hospitals and ASCs, is usually accomplished in four to eight hours.

Citing a Deficiency

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

When facilities have identified deficient practice, surveyors usually 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. All risk management deficiencies are cited on a separate state deficiency statement that is confidential and protected under KSA 65-4925.

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 where 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 that this may change in the future, if the risk management laws are revised.

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

Surveyors answer risk management questions during the risk management survey process. On an ongoing basis, the Risk Management Specialist is available to provide education and answer questions for the medical care facilities. Many Kansas facilities had a changeover of risk managers during the interim between surveys. Per survey findings and as reported by risk management staff, some new and experienced risk managers fail to protect the reporter's name, to assure that risk management information is secured at all times, and/or to take immediate action when an error occurs. Some risk managers do not investigate "near misses" and/or identifying root causes to pinpoint effective interventions, including improved processes, to further minimize occurrences. The risk management surveyors evaluate the facilities for compliance with the Kansas Risk Management statutes and regulations and with implementation of an effective risk management program. In 2010, the average risk management survey included seven hours of on-site survey time.

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

Risk management regulation KAR 28-52-4 mandates that facilities assign a separate standard of care for each involved provider, and each clinical issue. Finding the individual providers involved with the incident and determining a standard of care for those providers has been the focus of risk management for many years. There is a difference between involved and culpable. Per Merriam-Webster's Desk Dictionary published in 2002:

Involved means "drawn in," "envelop," "connect," "include," have a part of."

Culpable means "deserving blame."

There continues to be confusion about who is involved. The June 2009 and June 2010 Risk Management Mailbags discuss identifying involved providers. These and other Risk Management resources are available on the KDHE web site: http://www.kdheks.gov/bhfr/state_ach_licensure_forms.html

The Risk Management Specialist

The KDHE's Risk Management Specialist is involved in many risk management activities. Those activities included, but were not limited to, risk management plan review/approval, provision of training/consultation to providers and surveyors, and oversight of the program.

The turnover of risk managers throughout the state continues and many are placed in their positions without training or orientation. In 2010, the Risk Management Specialist provided educational programs for medical care facilities throughout the state, both in a group setting and on an individual basis.

Risk Management Goals for 2011

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

- Assist facilities in improving the risk management process through educational programs and consultation and availability of risk management resources on the KDHE web site;
- Share information accumulated from literature, the direct involvement with other states and the direct involvement with 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:

Risk Management Specialist
Bureau of Child Care and Health Facilities
Kansas Department of Health and Environment
1000 SW Jackson, Suite 200
Topeka, Kansas 66612-1274

Statistical Information

for

Risk Management/Licensure and Certification

Survey Process

Glossary of Terms

Tables

Appendices

Frequently Cited Tags

Glossary of Terms

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

Tables Introduction

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

Table 1*
Comparison of Reportable SOC's By Year and By Licensing Agency 2001 – 2010

Year	Total # of Reportable SOC's	SO CIII	SOC IV	KSBHA	KSBN	KDHE	KBP	Other
2001	436	320	116	48 (11%)	208 (48%)	149 (34%)	14 (3%)	17 (4%)
2002	501*	395	106	57 (12%)	222 (47%)	149 (34%)	14 (3%)	16 (3%)
2003	572***	447	126	22 (16.1%)	43 (31.4%)	62 (45.3%)	8 (5.8%)	2 (1.4%)
2004	519****	388	131	61 (11.3%)	233 (43%)	219 (40.4%)	10 (1.8%)	19 (3.5%)
2005	640****	371	269	44 (6.9%)	339 (53%)	219 (34.2%)	22 (3.4%)	16 (2.5%)
2006	531*****	427	104	68 (12.8%)	243 (45.8%)	166 (31.3%)	32 (6%)	22 (4.1%)
2007	548*****	412	136	71 (13%)	249 (45.4%)	196 (35.8%)	18 (3.3%)	14 (2.5%)
2008	703*****	532	171	59 (8.4%)	401 (57%)	214 (30.5%)	14 (2%)	15 (2.1%)
2009	608*****	460	148	50 (8.2%)	407 (66.9%)	136 (22.3%)	8 (1.3%)	8 (1.3%)
2010	507*****	376	131	53 (10.4%)	298 (58.8%)	134 (26.4%)	11(2.2%)	11(2.2%)

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

**The 2002 total number of SOC's by all providers was 93,627 with 501 SOC III's and SOC IV's or .535%.

***The 2003 total number of SOC's by all providers was 87,359 with 572 SOC III's and SOC IV's or .655%, an increase.

****The 2004 total number of SOC's by all providers was 89,306 with 519 SOC III's and SOC IV's or .581%, a decline.

****The 2005 total number of SOC's by all providers was 96,726 with 640 SOC III's and SOC IV's or .66%, an increase.

****The 2006 total number of SOC's by all providers was 107,293 with 631 SOC III's and SOC IV's or .485%, a decline.

*****The 2007 total number of SOC's by all providers was 101,447 with 548 SOC III's and SOC IV's or .54%, an increase.

*****The 2008 total number of SOC's by all providers was 109,072 with 703 SOC III's and SOC IV's or .645%, an increase.

*****The 2009 total number of SOC's by all providers was 132,534 with 608 SOC III's and SOC IV's or .459%, a decline.

*****The 2010 total number of SOC's by all providers was 146,404 with 507 SOC III's and SOC IV's or .347%, a decline, and all time low.

Table 2
Comparison of Total Number of Reportable Incidents Generated By Facility Size and Licensing Agency
2001-2010

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
1-25 beds	2010	18 (14%)	59 (45.7%)	41 (31.8%)	4(3.1%)	7 (5.4%)
	2009	5 (3.5%)	115 (79.8%)	22 (15.3%)	1(0.7%)	1 (0.7%)
	2008	25 (17%)	84 (57.2%)	31 (21.1%)	3 (2%)	4 (2.7%)
	2007	16 (10.5%)	79 (51.9%)	48 (31.6%)	5 (3.3%)	4 (2.7%)
	2006	21 (12.1%)	61 (35.3%)	55 (31.8%)	15 (8.7%)	21 (12.1%)
	2005	16 (9.5%)	59 (34.9%)	89 (52.4%)	2 (1.2%)	3 (1.8%)
	2004	18 (14%)	40 (31%)	59 (46%)	1 (1%)	10 (8%)
	2003	19 (13.6%)	79 (56.5 %)	32 (22.8%)	8 (5.7%)	1 (1.4%)
	2002	6 (7%)	29 (32%)	53 (38%)	1 (1%)	3 (3%)
	2001	4 (5%)	36 (45%)	34 (42%)	1 (1%)	6 (7%)
26-50 beds	2010	4 (16%)	14 (56%)	7 (28%)	0	0
	2009	0	20 (74.1%)	3 (11.1%)	2 (7.4%)	2 (7.4%)
	2008	2 (3%)	40 (60.7%)	22 (33.3%)	0	2 (3%)
	2007	15 (38.5%)	15 (38.5%)	9 (2.23%)	0	0
	2006	2 (6.5%)	16 (51.6%)	1 (3.2%)	3 (9.7%)	9 (29%)
	2005	1 (3.3%)	20 (66.7%)	8 (26.7%)	0	1 (3.3%)
	2004	4 (6%)	29 (40%)	39 (54%)	0	0
	2003	23 (23.9%)	35 (38%)	28 (34.4%)	5 (5.4%)	1 (1%)
	2002	9 (13%)	38 (53%)	22 (31%)	3 (4%)	0
	2001	17 (24%)	36 (50%)	20 (28%)	3 (4%)	3 (4%)
51-100 beds	2010	5 (11.9%)	28 (66.7%)	7 (16.7%)	0	2 (4.7%)
	2009	18 (27.7%)	33 (50.8%)	13 (20%)	0	1 (1.5%)
	2008	3 (2.2%)	110 (82.1%)	18 (13.4%)	2 (1.5%)	1 (.8%)
	2007	5 (10.2%)	23 (51%)	12 (24.5%)	1 (2%)	5 (10.2%)
	2006	15 (22.4%)	44 (65.7%)	0	1 (1.5%)	7 (10.4%)
	2005	3 (3.9%)	41 (53.2%)	13 (16.9%)	16 (20.8%)	4 (5.2%)
	2004	5 (12%)	24 (56%)	7 (16%)	2 (5%)	5 (12%)
	2003	4 (11%)	17 (41.5%)	15 (36.6%)	0	2 (4.9%)
	2002	6 (9%)	25 (36%)	34 (49%)	2 (3%)	2 (3%)
	2001	4 (11%)	21 (54%)	9 (24%)	0	4 (11%)

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
101-200 beds	2010	10 (20%)	33 (66%)	4 (8%)	2 (4%)	1 (2%)
	2009	7 (10.1%)	51 (73.9%)	9 (13%)	1 (1.5%)	1 (1.5%)
	2008	4 (26.7%)	5 (33.3%)	4 (26.7%)	0	1 (13.3%)
	2007	15 (25.9%)	29 (50%)	4 (6.9%)	9 (15.5%)	1 (1.7%)
	2006	13 (36.1%)	18 (50%)	1 (2.8%)	0	4 (11.1%)
	2005	4 (9.3%)	35 (81.4%)	2 (4.6%)	0	2 (4.6%)
	2004	18 (17%)	65 (65%)	21 (19%)	3 (3%)	1 (1%)
	2003	0	10 (52.6%)	9 (47.4%)	0	0
	2002	9 (17%)	36 (67%)	8 (15%)	1 (2%)	0
	2001	6 (11%)	38 (69%)	10 (18%)	0	1 (2%)
201+ beds	2010	16 (6.2%)	163 (63.2%)	73 (28.3%)	5 (1.9%)	1 (0.4%)
	2009	11 (4.6%)	155 (64.6%)	68 (28.3%)	4 (1.7%)	2 (0.8%)
	2008	21 (6.3%)	160 (47.9%)	139 (41.6%)	8 (2.4%)	6 (1.8%)
	2007	16 (7%)	101 (41%)	122 (50%)	3 (1%)	3 (1%)
	2006	13 (6.5%)	96 (47.8%)	5 (2.5%)	6 (3%)	81 (40.3%)
	2005	18 (5.3%)	181 (57.8%)	104 (33.2%)	4 (1.3%)	6 (1.9%)
	2004	14 (10%)	2 (19%)	91 (65%)	4 (3%)	3 (2%)
	2003	19 (48.7%)	1 (2.5 %)	17 (41.5%)	1 (2.6%)	1 (2.6%)
	2002	13 (8%)	87 (50%)	59 (34%)	8 (5%)	6 (3%)
	2001	17 (9%)	85 (45%)	76 (40%)	10 (5%)	3 (1%)
ASCs	2010	0	1 (33.3%)	2 (66.7%)	0	0
	2009	2 (15.4%)	5 (38.5%)	6 (46.1%)	0	0
	2008	4(57.1%)	2 (28.6%)	0	1 (14.3%)	0
	2007	3 (43%)	0	3 (43%)	0	1 (14%)
	2006	4 (20%)	8 (40%)	0	1 (5%)	7 (35%)
	2005	2 (25%)	3 (37.5%)	3 (37.5%)	0	0
	2004	2 (29%)	3 (43%)	2 (28%)	0	0
	2003	0	0	0	0	0
	2002	1 (8%)	0	3 (23%)	0	9 (69%)
	2001	0	0	0	0	0

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

Table 3

Comparison of Average Number of SOCs and Reportable SOCs Filed By Facility Size 2005 – 2010

Facilities by Bed Size/ Category	Number of Facilities in Size Category 2008	Avg # of SOCs/ Total # of Reportable SOCs 2005	Avg # of SOCs/ Total # of Reportable SOCs 2006	Avg # of SOCs/ Total # of Reportable SOCs 2007	Avg # of SOCs/ Avg # of Reportable SOCs /Avg # of Incidents 2008	Avg # of SOCs/ Avg # of Reportable SOCs /Avg # of Incidents 2009	Avg # of SOCs/ Avg # of Reportable SOCs 2010
1 - 25	93	296.9/169	351/176	408.4/152	380.4/1.6/250.8	557.3/2.1/327.5	553.4/1.4
26 - 50	15	492.8/30	501.8/31	544.2/39	1329.4/5.1/942.8	515.4/1.8/358.5	500.1/1.7
51 - 100	23	555.8/77	596.8/67	524.9/49	615.3/5.7/586.3	603.8/2.8/515.9	606.4/2.2
101 - 200	12	703.4/43	1049/36	1221.5/58	517.2/1.2/447.1	1173.4/5.7/1037.7	1380.5/4.2
200 +	13	2873/313	3044/201	2701/243	4661.3/25.7/3955.6	3263.8/18.5/3352.1	4181.8/19.5
ASCs	67	39.6/8	37/20	34.8/7	35.6/10.8/24.7	37.5/0.19/26.4	38.1/0.45
Totals	223	469.5/640	506.1/531	501.9/548	620.2/3.2/481.3	591.6/2.7/473.1	656.5/2.27

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

KDHE RISK MANAGEMENT ARTICLES

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

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

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

39. **"Primum non nocere,"** Wikipedia
40. **"Medical Errors Cost U.S. \$8.8 Billion, result in 238, 337 potentially preventable deaths, according to HealthGrades Study,"** HealthGrades article appeared on 4/8/08
41. **"Medicare to Cut Payments for Avoidable Errors,"** by Julie Rovner. Article appeared on 8/22/07.
42. **"Medicare Won't Pay for Medical Errors,"** by Kevin Sack. Article appeared in The New York Times on 10/1/08.
43. **"Medicare this week stops paying for the cost of preventable hospital errors,"** published 9/29/08 on Everything Cleveland.
44. **"THE DIRECT MEDICAL COSTS OF Healthcare-Associated infections in U.S. Hospitals and the Benefits of Prevention,"** CDC, March 2009
45. **"Pressure Ulcers and Wound Care,"** by Dr Richard Salcido MD and Adrian Popescu, MD, with the University of Pennsylvania School of Medicine. The updated 7/9/10 article appeared on eMedicine.
46. **Premier Safety Institute** release, 9/28/09
47. **"Checklist helps reduce CBSI rate to near zero,"** Nursing 2010, April 2010
48. **Do No Harm** quote, www.donoharm.us
49. **"The Doctor Can Understand You Now,"** US News, 9/23/09
50. **Carl W Buechner** quotes, Thinkexist.com
51. ***"The Best Interest of the Patient,"*** 1910 address to graduating class of Rush College, mayoclinic.org
52. ***"Diagnosis-Related Groups,"*** Wikipedia
53. ***"Electronic Records at a Glance,"*** CMS Office of Public Affairs, 7/13/10

APPENDIX A

Total of Survey Codes Cited During 12 **Acute Care Hospital** Licensure/Certification Surveys 2010

SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES	SURVEY CODES	# OF CITES
H0025	1	A0148	1	A0310	1	A0493	1	A0724	1
H0044	1	A0166	2	A0338	1	A0501	1	A0747	5
H0063	1	A0168	3	A0340	1	A0502	4	A0748	1
H0113	1	A0169	1	A0341	1	A0505	5	A0749	2
H0114	1	A0172	1	A0347	1	A0506	1	A0750	1
		A0173	1	A0354	1	A0511	2	A0756	1
		A0174	1	A0358	1	A0528	1	A0940	1
A0020	1	A0175	2	A0385	1	A0536	1	A0945	1
A0021	1	A0176	1	A0395	1	A0537	1	A0951	1
A0023	1	A0194	1	A0396	2	A0538	1	A0952	1
A0048	1	A0196	2	A0397	1	A0546	1	A1151	1
A0049	1	A0199	1	A0398	1	A0547	1	A1153	1
A0067	1	A0200	1	A0404	1	A0576	1	A1154	1
A0083	1	A0201	1	A0406	1	A0582	1	A1508	1
A0084	2	A0202	1	A0409	2	A0583	1	A1513	1
A0085	1	A0204	2	A0410	1	A0584	1	A1516	1
A0093	1	A0205	1	A0431	2	A0585	1	A1517	1
A0115	3	A0207	1	A0432	1	A0592	1	A1519	1
A0117	2	A0208	2	A0441	1	A0618	1	A1537	2
A0118	1	A0214	1	A0449	1	A0620	1	A2400	3
A0131	2	A0263	2	A0450	5	A0621	1	A2404	1
A0132	1	A0265	1	A0454	3	A0628	1	A2405	1
A0133	1	A0267	3	A0458	1	A0700	3	A2406	1
A0143	2	A0275	1	A0466	1	A0701	3	A2407	1
A0144	2	A0276	1	A0469	3	A0703	1	A2411	1
A0145	1	A0277	1	A0490	1	A0709	1		
A0147	1	A0287	1	A0492	4	A0722	1		

APPENDIX B

Total of Survey Codes Cited During 22 Critical Access Hospital Licensure and Certification Surveys 2010

SURVEY CODES	# of CITES	SURVEY CODES	# of CITES	SURVEY CODES	# of CITES	SURVEY CODES	# of CITES
H0010	2	C0154	1	C0279	2	C0361	2
H0012	3	C0202	1	C0280	4	C0368	1
H0038	1	C0203	1	C0281	6	C0369	1
H0040	1	C0204	2	C0283	1	C0381	1
H0041	5	C0211	1	C0291	4	C0382	1
H0043	1	C0220	1	C0297	1	C0384	1
H0044	1	C0222	5	C0298	3	C0385	4
H0052	1	C0224	2	C0300	1	C0386	2
H0064	2	C0225	4	C0301	1	C0388	3
H0068	1	C0227	1	C0302	2	C0390	1
		C0228	1	C0304	1	C0395	3
		C0229	1	C0306	2	C2400	1
		C0230	1	C0307	9	C2402	1
		C0240	3	C0308	2	C2406	2
		C0241	4	C0330	2	C2407	1
		C0258	1	C0334	4		
		C0265	1	C0335	1		
		C0270	5	C0336	2		
		C0271	1	C0337	4		
		C0272	4	C0338	2		
		C0276	7	C0345	2		
		C0277	3	C0350	3		
		C0278	12	C0360	1		

APPENDIX C

Total of Survey Codes Cited During 30 **Ambulatory Surgical Center** Licensure and Certification Surveys
2010

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
S0110	1	Q0080	4	Q0231	1
S0145	1	Q0081	4	Q0232	1
S0265	1	Q0082	4	Q0233	3
S0350	1	Q0083	4	Q0234	2
S0375	5	Q0084	4	Q0240	3
S0500	3	Q0101	2	Q0241	6
S0575	3	Q0103	2	Q0242	5
S0580	1	Q0105	1	Q0243	1
		Q0122	2	Q0244	3
		Q0141	1	Q0245	2
		Q0162	4	Q0261	3
		Q0181	5	Q0262	1
		Q0184	1	Q0263	2
		Q0201	1	Q0264	1
		Q0220	1	Q0266	2
		Q0221	4	Q0267	1
		Q0223	1		
		Q0224	2		
		Q0225	1		
Q0040	3	Q0226	1		
Q0041	4	Q0227	2		
Q0042	1	Q0228	1		
Q0043	2	Q0229	1		
Q0060	3	Q0230	2		

APPENDIX D

Total of Survey Codes cited During 50 Hospital, CAH and ASC **Risk Management** Surveys 2010

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
R0801	5	R0813	4	R0832	1
R0803	1	R0815	2	R0833	13
R0807	5	R0820	2	R0835	1
R0808	3	R0829	2		
R0809	3	R0830	2		
R0810	1	R0831	2		

APPENDIX E

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 12 **Hospital** Certification & Licensure 2010

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
A0749 – Infection Control Officer Responsibilities	10	83%
A0450 – Medical Records Services	5	42%
A0505– Unusable Drugs Not in Use	5	42%
A0747 – Infection Control	5	42%

APPENDIX F

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 22 **CAH Hospital** Certification Surveys 2010

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
C0278 – Patient Care Policies	16	73%
C0276 – Patient Care Policies	14	34%
C0307 – Records System	9	41%
C0281 – Direct Services	6	27%
C0222 – Maintenance	5	23%
C0270 – Provision of Services	5	23%

APPENDIX G

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 48 **Hospital & CAH** Risk Management Surveys 2010

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
R0833 – Separate SOC per provider and clinical issue	13	31%
R0807 – Risk Management plan included name and address of the facility and name and title of the facility’s risk manager	4	9%
R0801 – Plan reviewed and approved by the Governing Body annually	3	7%
R0808 –Plan includes names and titles of medical staff members involved in investigation and review of reportable incidents.	3	7%
R0809 – Plan includes an organizational chart indicating position of the facility’s risk management committee(s) and lines of authority	3	7%
R0813 – Plan amendment(s) are submitted to KDHE for approval	3	7%

APPENDIX H

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During **ASC** Surveys – 30 Certification & Licensure and 28 Risk Management Surveys 2010

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
Q0241 – Sanitary Environment	6	20%
Q0181 – Administration of Drugs	5	17%
Q0242 – Infection Control	5	17%
S0375 – Human Resources	5	17%

APPENDIX I

2010 Cited Survey Codes

State Licensure and Federal Certification Acute Care Hospital:

H0025 **KAR 28-34-6a(g)(2)** A practitioner may give verbal orders, including telephone orders, for medication or treatment to personnel who are qualified according to medical staff bylaws. The person entering these orders into the medical record shall sign and date the entry as soon as possible. These orders shall be authenticated by the prescribing or covering practitioner within 72 hours of the patient's discharge or 30 days, whichever occurs first.

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

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

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

- (A) Equipment appropriate for maternal and newborn resuscitation, including suction, airways, endotracheal tubes, and ambu bags;
- (B) equipment for administration of inhalation and regional anesthetics;
- (C) a functioning source of emergency electrical power;
- (D) an emergency call or intercommunication system;
- (E) oxygen and suction equipment which can be accurately regulated;
- (F) a fetal monitor;
- (G) supplies and instruments for emergency Cesarean section;
- (H) a scrub sink with foot, knee, or elbow control;
- (I) prophylactic solution approved by the licensing agency for instillation into eyes of newborn pursuant to K.S.A. 64-153 and K.A.R. 28-4-73 and any amendments thereto;
- (J) a method for identification of the newborn and mother;
- (K) a movable, heated bassinet, a bassinet with a radian warmer, or a transport isolette for the newborn while in the delivery room and during transport from the delivery room; and
- (L) a sink with foot, knee, or elbow control.

A0020 **CFR 482.11** Compliance with Laws Condition of Participation

A0021 **CFR 482.11(a)** The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

A0023 **CFR 482.11(c)** The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

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

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

A0048 **CFR 482.12(a)(4)** [The governing body must] approve medical staff bylaws and other medical staff rules and regulations.

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

A0067 **CFR 482.12(c)(3)** [...the governing body must ensure that the following requirements are met:] A doctor of medicine or osteopathy is on duty or on call at all times.

A0083 **CFR 482.12(e)** The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

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

A0085 **CFR 482.12(e)(2)** The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

A0093 **CFR 482.12(f)(2)** If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

A0115 **CFR 482.13** A hospital must protect and promote each patient's rights.

A0117 **CFR 482.13(a)(1)** A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

A0118 **CFR 482. 13(a)(2)** The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

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

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

- A0132 **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).
- A0133 **CFR 482.13(b)(4)** The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.
- A0143 **CFR 482.13(c)(1)** The patient has the right to personal privacy.
- A0144 **CFR 482.13(c)(2)** The patient has the right to receive care in a safe setting.
- A0145 **CFR 482.13(c)(3)** The patient has the right to be free from all forms of abuse or harassment.
- A0147 **CFR 482.13(d)(1)** The patient has the right to the confidentiality of his or her clinical records.
- A0148 **CFR 482.13(d)(2)** The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.
- A0166 **CFR 482.13(e)(4)(i)** The use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care.
- A0168 **CFR 482.13(e)(5)** The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.
- A0169 **CFR 482.13(e)(6)** Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).
- A0172 **CFR 482.13(e)(8)** [Unless superseded by State law that is more restrictive,] after 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.
- A0173 **CFR 482.13(e)(8)** [Unless superseded by State law that is more restrictive,]
(iii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.
- A0174 **CFR 482.13(e)(10)** The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.
- A0175 **CFR 482.13(e)(10)** The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.
- A0176 **CFR 482.13(e)(11)** Physician and other licensed independent practitioner training requirements must be specified in hospital policy.

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

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

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

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

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

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

- (ii) The use of nonphysical intervention skills.

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

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

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

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

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

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

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

A0207 **CFR 482.13(f)(3)** Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

A0208 **CFR 482.13(f)(4)** Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

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

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

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

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

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

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

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

A0276 **CFR 482.21(b)(2)(ii)** [The hospital must use the data collected to--] (ii) Identify opportunities for improvement and changes that will lead to improvement.

A0277 **CFR 482.21(b)(3)** [The hospital must use the data collected to--] (ii) Identify opportunities for improvement and changes that will lead to improvement.

A0287 **CFR 482.21(c)(2)** [Performance improvement activities must track medical errors and adverse patient events,] and analyze their causes, and ...

A0301 **CFR 482.21(d)(3)** [Performance improvement activities must track medical errors and adverse patient events,] and analyze their causes, and ...

A0310 **CFR 482.21(e)(1)** That an ongoing program for quality improvement ... is defined, implemented, and maintained.

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

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

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

A0347 **CFR 482.22(b)** The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

A0354 **CFR 482.22(c)(1)** [The bylaws must:] (1) Be approved by the governing body.

A0358 **CFR 482.22(c)(5)** [The bylaws must:] Include a requirement that-- (i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified individual in accordance with State law and hospital policy.

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

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

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

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

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

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

A0406 **CFR 482.23(c)(2)** With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).

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

A0410 **CFR 482.23(c)(4)** With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).

A0431 **CFR 482.24** The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

A0432 **CFR 482.24(a)** The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

A0441 **CFR 482.24(b)(3)** 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.

A0449 **CFR 482.24(c)** 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.

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

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

A0458 **CFR 482.24(c)(2)** All records must document the following, as appropriate:
(i) Evidence of-- (A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

A0466 **CFR 482.24(c)(2)(v)** [All records must document the following, 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.

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

A0490 **CFR 482.25** The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

A0492 **CFR 482.25(a)(1)** A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

A0493 **CFR 482.25(a)(2)** The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

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

- A0502 **CFR 482.25(b)(2)(i)** All drugs and biologicals must be kept in a secure area, and locked when appropriate.
- A0505 **CFR 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.
- A0506 **CFR 482.25(b)(4)** When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.
- A0511 **CFR 482.25(b)(9)** A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.
- A0528 **CFR 482.26** The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.
- A0536 **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.
- A0537 **CFR 482.26(b)(2)** Periodic inspection of equipment must be made and hazards identified must be promptly corrected.
- A0538 **CFR 482.26(b)(3)** Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.
- A0546 **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.
- A0547 **CFR 482.26(c)2** Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
- A0576 **CFR 482.27** The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter.
- A0582 **CFR 482.27(a)** The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets the requirements of part 493 of this chapter.
- A0583 **CFR 482.27(a)(1)** Emergency laboratory services must be available 24 hours a day.
- A0584 **CFR 482.27(a)(2)** A written description of services provided must be available to the medical staff.
- A0585 **CFR 482.27(a)(3)** The laboratory must make provisions for the proper receipt and reporting of tissue specimens.
- A0592 **CFR 482.27(b)** Standard: Potentially infectious blood and blood products.

(1) Potentially human immunodeficiency virus (HIV) infectious blood and blood components. Potentially HIV infectious blood and blood components are prior collections from a donor -

(i) Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;

(ii) Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and

(iii) For whom the timing of seroconversion cannot be precisely estimated.

(2) Potentially hepatitis C virus (HCV) infectious blood and blood components. Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.

(3) Services furnished by an outside blood collecting establishment. If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital --

(i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;

(ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA;

(iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).

(4) Quarantine of blood and blood components pending completion of testing. If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood component and quarantine all blood and blood components from previous donations in inventory.

(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must -

(A) Dispose of the blood and blood components; and

(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section.

(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).

(5) Recordkeeping by the hospital. The hospital must maintain --

(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

(6) Patient notification. If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or appropriate individual, the hospital must take the following actions:

(i) Make reasonable attempts to notify the patient, or to notify the attending physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under

paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian or relative.

(iii) Document in the patient's medical record the notification or attempts to give the required notification.

(7) Timeframe for notification.

(i) For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless--

(A) The patient is located and notified; or

(B) 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 12 weeks.

(ii) For donors tested before February 20, 2008. For notifications from donors tested before February 20, 2008 as set forth at 21 CFR 610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment.

(8) Content of notification. The notification must include the following information:

(i) A basic explanation of the need for HIV or HCV testing and counseling.

(ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling.

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) 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 the confidentiality of medical records and other patient information.

(10) 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. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(11) Applicability. HCV notification requirements resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48 will expire on August 24, 2015.

A0618 **CFR 482.28** The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

A0620 **CFR 482.28(a)(1)** The hospital must have a full-time employee who-

(i) Serves as director of the food and dietetic services;

- (ii) Is responsible for daily management of the dietary services; and
- (iii) Is qualified by experience or training.

A0628 **CFR 482.28(b)** Menus must meet the needs of the patients.

A0700 **CFR 482.41** The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

A0701 **CFR 482.41(a)** The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

A0703 **CFR 482.41(a)(2)** There must be facilities for emergency gas and water supply.

A0709 **CFR 482.41(b)** Life Safety from Fire

A0722 **CFR 482.41(c)** The hospital must maintain adequate facilities for its services.

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

A0747 **CFR 482.42** The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

A0748 **CFR 482.42(a)** A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

A0749 **CFR 482.42(a)(1)** The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

A0750 **CFR 482.42(a)(2)** The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

A0756 **CFR 482.42(b)** Standard: Responsibilities of chief executive officer, medical staff and director of nursing services. The chief executive officer, the medical staff, and the director of nursing must--
(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and
(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

A0940 **CFR 482.51** If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

A0945 **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.

A0951 **CFR 482.51(b)** Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

A0952 **CFR 482.51(b)(1)** Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

A1151 **CFR 482.57(a)** The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

A1153 **CFR 482.57(a)(1)** There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

A1154 **CFR 482.57 (a)(2)** There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

A1508 **CFR 482.66(b)(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.

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

A1516 **CFR 482.66(b)(1)** The resident has the right to privacy in written communications, including the right to send and promptly receive mail that is unopened; and have access to stationery, postage, and writing implements at the resident's own expense.

A1517 **CFR 482.66(b)(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.

A1519 **CFR 482.66(b)(1)** The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

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

The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who is licensed or registered, if applicable, by the State in which practicing; and is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program

in a health care setting; or is a qualified occupational therapist or occupational therapy assistant; or has completed a training course approved by the State.

A2400 **CFR 489.20(I)** The provider agrees, in the case of a hospital as defined in §489.24(b), to comply with §489.24.

A2404 **CFR 482.20®(2) and 489.24(j)(1-2)**
489.20(r)(2)

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

§489.24(j)(1)

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

§489.24(j)(2)(i)

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

§489.24(j)(2)(ii)

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

A2405 **CFR 482.20(r)(3)** [The provider agrees,] in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

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

A2406 **CFR 482.24(1) and 489.24(c)** Applicability of provisions of this section.

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

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

(2) Nonapplicability of provisions of this section.

Sanctions under this section for inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided for by section 1135(e)(1)(B) of the Act.

(c) Use of Dedicated Emergency Department for Nonemergency Services

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

A2407 **CFR 489.24(d)(1-3)** (1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either-

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

(2) Exception: Application to inpatients.

(i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment.

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

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

State Licensure and Federal Certification Critical Access Hospitals:

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

H0012 **KAR 28-34-4a** Visitors. (a) Each hospital shall establish visitation policies which are in the interest of the patients. Children under 12 years of age shall not be admitted as visitors to the hospital except in the company of a responsible adult. Children under six years of age shall be admitted as visitors only when the hospital has a special family visiting program or when authorized in writing by the attending physician or the chief executive officer of the hospital, or the professional nurse charged with the responsibility for the care of the patient.

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

H0040 **KAR 28-34-8a(d)(1)** Personnel policies and procedures. The governing body, through the chief executive officer, shall establish and maintain written personnel policies and procedures which adequately support sound patient care. These policies and procedures shall be made available to all employees and shall be reviewed at least every two years. A procedure shall be established for advising employees of policy and procedure changes.

H0041 **KAR 28-34-8a(d)(2)** 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 current information regarding periodic work performance evaluations

H0043 **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.

H0052 **KAR 28-34-9a(d)(3)** A summary shall be maintained of medical records which have been destroyed. This summary shall be retained on file for at least 25 years and shall include the following information: (A) the name, age, and date of birth of the patient; (B) the name of the patient's nearest relative; (C) the name of the attending and consulting practitioners; (D) any surgical procedure and date, if applicable; and (E) the final diagnosis.

H0064 **KAR 28-34-10a(e)** Policies and procedures. The pharmaceutical service shall develop written policies and procedures. These policies shall be reviewed by the medical staff at least annually and shall be dated to indicate the date of last review. Procedures shall be established for the recording of all drug dispensations or other pharmacy transactions of the pharmacy or nursing stations.

H0068 **KAR 28-34-13(c)** Sterilizers and autoclaves shall be provided of appropriate type and necessary capacity to adequately sterilize instruments, utensils, dressings, water, operating and delivery

room materials, as well as laboratory equipment and supplies. The sterilizers shall have approved control and safety features. The accuracy of instruments shall be checked periodically by an approved method. Adequate surveillance methods for checking sterilization procedures shall be employed.

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

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

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

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

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

C0220 **CFR 485.623** Physical Plant and Environment

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

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

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

C0227 **CFR 485.623(c)(1)** The CAH assures the safety of patients in non-medical emergencies by-- training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

C0228 **CFR 485. 623(c)(2)** [The CAH assures the safety of patients in non-medical emergencies by-- providing for emergency power and lighting in the emergency room and for battery lamps and flashlight in other areas;

C0229 **CFR 485.623(c)(3)** [The CAH assures the safety of patients in non-medical emergencies by-- (3) providing for an emergency fuel and water supply; and.

C0230 **CFR 485. (c)(4)** [The CAH assures the safety of patients in non-medical emergencies by--] taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

C0240 **CFR 485.627** Organizational Structure

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

C0258 **CFR 485.631(b)(1)(ii)** [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;

C0265 **CFR 485.631(c)(1)(i)** The physician assistant, 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; [and]

C0270 **CFR 485.635** Provision of Services

C0271 **CFR 485.635(a)(1)** The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

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

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

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

C0278 **CFR 485.635(a)(3)(vi)** [The policies include the following:]
(vi) 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 the following:]

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 posthospital SNF care.

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

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

C0283 **CFR 485.635(b)(3)** Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

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

C0297 **CFR485.635(d)(3)** All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

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

C0300 **CFR 485.638** Clinical Records

C0301 **CFR 485.638(a)(1)** The CAH maintains a clinical records system in accordance with written policies and procedures.

C0302 **CFR 485. 638(a)(2)** The records are legible, complete, accurately documented, readily accessible, and systematically organized.

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

(i) identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

C0306 **CFR 485.638(a)(4)(iii)** [For each patient receiving health care services, the CAH maintains a record that includes, as applicable-] all orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics and progress notes describing the patient's response to treatments; [and]

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

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

C0330 **CFR 485.641** Periodic Evaluation and Quality Assurance Review

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

C0334 **CFR 485.641(a)(1)(iii)** [The evaluation is done at least once a year and includes review of--]
(i) the CAH's health care policies.

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

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

C0337 **CFR 485.641(b)(1)** The quality assurance program requires that all patient care services and other services affecting patient health and safety are evaluated.

C0338 **CFR 485.641(b)(2)** [The program requires that--] nosocomial infections and medication therapy are evaluated;

C0345 **CFR 485.643(a)** [The CAH must have and implement written protocols that:] incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

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

C0360 **CFR 485. 645(d)** The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h),(i), (j)(1)(vii) and (viii), (1), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).

(3) Resident behavior and facility practices (§483.13 of this chapter).

(4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§483.15(g) of this chapter).

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

(7) Specialized rehabilitative services (§483.45 of this chapter).

(8) Dental services (§483.55 of this chapter).

(9) Nutrition (§483.25(i) of this chapter).

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

(1) Resident rights (§483.10(b)(3)):

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

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.

C0373 **CFR 485. 645(d)(2)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:]

Transfer, and discharge rights (§483.12(a)) :

"(1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility."

C0379 **CFR 485.** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:]

Transfer, and discharge rights (§483.12(a)(6)):

"The written notice specified in paragraph (a)(4) of this section must include the following:

- (i) The reason for transfer or discharge;
- (ii) The effective date of transfer or discharge;
- (iii) The location to which the resident is transferred or discharged;
- (iv) A statement that the resident has the right to appeal the action to the State;
- (v) The name, address and telephone number of the State long term care ombudsman;
- (vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and
- (vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act."

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

C0382 **CFR 485.645(d)(3)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:]

Transfer, and discharge rights (§483.12(a)(6)):

"The written notice specified in paragraph (a)(4) of this section must include the following:

- (i) The reason for transfer or discharge;
- (ii) The effective date of transfer or discharge;
- (iii) The location to which the resident is transferred or discharged;
- (iv) A statement that the resident has the right to appeal the action to the State;

- (v) The name, address and telephone number of the State long term care ombudsman;
- (vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and
- (vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act."

C0384 **CFR 485.645(d)(3)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:]

Resident behavior and facility practices (§483.13(c)(1)(ii) - (iii) & (2-4)):

"The facility must-

- (ii) Not employ individuals who have been-
 - (A) 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."

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

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

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

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

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

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

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

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

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

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

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge potential.

(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(xviii) Documentation of participation in assessment.

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

C0390 **CFR 485.645(d)(6)** [The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

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

Comprehensive assessment - when required ((§483.20(b)(2))

"(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that

has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months."

C0395 **CFR 485. 645(d)(6)** The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment.

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

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

C2402 **CFR 489.20(q)** [The provider agrees,] in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

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

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

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

(2) Nonapplicability of provisions of this section.

Sanctions under this section for inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided for by section 1135(e)(1)(B) of the Act.

(c) Use of Dedicated Emergency Department for Nonemergency Services

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

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

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

(2) Exception: Application to inpatients.

(i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

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

State and Federal Certification for Ambulatory Surgical Centers:

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

S0265 **KAR 28-34-53(f)** The governing authority shall select and employ an administrator and shall notify the department of any change of administrator within five days after the change has been made.

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

S0500 **KAR 28-34-57(e)** Each record shall be dated and authenticated by the person making the entry.

Nursing notes and observations shall be signed and dated by the registered nurse or licensed practical nurse making the entry. Verbal orders by authorized individuals shall be accepted and transcribed only by designated personnel

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

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

Q0040 **CFR 416.41** The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.

Q0041 **CFR 416.41(a)** When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

Q0042 **CFR 416.41(b)** (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

(2) This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter.

(3) The ASC must -

(i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or

(ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.

Q0043 **CFR 416.41(c)** (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.

(2) The ASC coordinates the plan with State and local authorities, as appropriate.

(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.

Q0060 **CFR 416.42** Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC

Q0061 **CFR 416.42(a)(1)** A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

Q0080 **CFR 416.43** The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program.

Q0081 **CFR 416.43(a) and 416.43(c)(1)** (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

- (c)(1) The ASC must set priorities for its performance improvement activities that -
- (i) Focus on high risk, high volume, and problem-prone areas.
 - (ii) Consider incidence, prevalence, and severity of problems in those areas.
 - (iii) Affect health outcomes, patient safety, and quality of care.

Q0082 **CFR 416.43(b) and 416.(c)(2)(3)** (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

- (c)(1) The ASC must set priorities for its performance improvement activities that -
- (i) Focus on high risk, high volume, and problem-prone areas.
 - (ii) Consider incidence, prevalence, and severity of problems in those areas.
 - (iii) Affect health outcomes, patient safety, and quality of care.

Q0083 **CFR 416.43(d)** (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results

Q0084 **CFR 416.43(e)** The governing body must ensure that the QAPI program-

- (1) Is defined, implemented, and maintained by the ASC.
- (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.
- (3) Specifies data collection methods, frequency, and details.
- (4) Clearly establishes its expectations for safety.
- (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

Q0101 **CFR 416.44(a)(1)** The ASC must provide a functional and sanitary environment for the provision of surgical services.

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

Q0103 **CFR 416.44(a)(3)** [The ASC must provide a functional and sanitary environment for the provision of surgical services.]

The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

Q0105 **CFR 416.44(c)** A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

Q0122 **CFR 416.45(b)** Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

Q0141 **CFR 416.46(a)** Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

Q0162 **CFR 416.47(b)** The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

- (1) Patient identification.
- (2) Significant medical history and results of physical examination.
- (3) Pre-operative diagnostic studies (entered before surgery), if performed.
- (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.
- (5) Any allergies and abnormal drug reactions.
- (6) Entries related to anesthesia administration.
- (7) Documentation of properly executed informed patient consent.
- (8) Discharge diagnosis.

Q0181 **CFR 416.48(a)** Drugs must be prepared and administered according to established policies and acceptable standards of practice.

Q0184 **CFR 416.48(a)(3)** Orders given orally for drugs and biologicals must be followed by a written order signed by the prescribing physician.

Q0201 **CFR 416.49(a)** If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter.

Q0220 **CFR 416.50** The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights.

Q0221 **CFR 416.50(a)(1)** The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands.

Q0223 **CFR 416.50(a)(1)(ii)** The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.

Q0224 **CFR 416.50(a)(2)** The ASC must comply with the following requirements:

- (i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms.
- (ii) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.
- (iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

Q0225 **CFR 416.50(a)(3)(i)(v)(vi)(vii)** (i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC.

(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response.

(vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.

(vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.

Q0226 **CFR 416.50(a)(3)(ii)(iii)(iv)** (ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(iii) All allegations must be immediately reported to a person in authority in the ASC.

(iv) Only substantiated allegations must be reported to the State authority or the local authority, or both.

Q0227 **CFR 416.50(b)(1)(i)** The patient has the right to - Exercise his or her rights without being subjected to discrimination or reprisal.

Q0228 **CFR 416.50(b)(1)(ii)** [The patient has the right to -] Voice grievances regarding treatment or care that is (or fails to be) furnished.

Q0229 **CFR 416.50(b)(1)(iii)** [The patient has the right to -] Be fully informed about a treatment or procedure and the expected outcome before it is performed.

Q0230 **CFR 416.50(b)(2)(3)** (2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

Q0231 **CFR 416.50(c)(1)** The patient has the right to - Personal privacy

Q0232 **CFR 416.50(c)(2)** [The patient has the right to -] Receive care in a safe setting

Q0233 **CFR 416.50(c)(3)** [The patient has the right to -] Be free from all forms of abuse or harassment

Q0234 **CFR 416.50(d)** The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.

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

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

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

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

Q0244 **CFR 416.51(b)(2)** [The program is -] An integral part of the ASC's quality assessment and performance improvement program.

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

Q0261 **CFR 416.52(a)(1)** Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy.

Q0262 **CFR 416.52(a)(2)** Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy.

Q0263 **CFR 416.52(a)(3)** The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure.

Q0264 **CFR 416.52(b)** (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Post-surgical needs must be addressed and included in the discharge notes.

Q0266 **CFR 416.52(c)(2)** [The ASC must -] Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

Q0267 **CFR 416.52(c)(3)** [The ASC must -] Ensure all patients are discharged in the company of a responsible adult except those patients exempted by the attending physician.

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.

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

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

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

A) Name and address of the facility;

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

R0808 **KAR 28-52-1(e)(4)(C)** Plan format. Each submitted plan shall include the following: Section IV C) description of involvement and organizational structure of medical staff as related to risk

management program, including names and titles of medical staff members involved in investigation and review of reportable incidents;

R0809 **KAR 28-52-1(e)(4)(D)** Plan format. Each submitted plan shall include the following: Section IV D) organizational chart indicating position of the facility's review committee as defined in K.S.A. 65-65-4923 and L. 1986, Ch. 229, new Section 4(a)(2);

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

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

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

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

R0819 **KSA 65-4923(a)(2)** If a health care provider, or a medical care facility agent or employee who is directly involved in the delivery of health care services, has knowledge that a health care provider has committed a reportable incident, such health care provider, agent or employee shall report such knowledge as follows:

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

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

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

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

R0821 **KSA 65-2924(a)** If a report to a state licensing agency pursuant to subsection (a)(1) of (2) of KSA 1986 Supp. 65-4923 or any other report or complaint filed with such agency relates to a health care provider's ability to practice the provider's profession with reasonable skill and safety due to physical or mental disabilities, including deterioration through the aging process, loss of motor skill or abuse of drugs or alcohol, the agency may refer the matter to an impaired provider committee of the appropriate state or county professional society or organization.

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

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

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

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

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

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

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

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

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