Regulation and Accreditation

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Introduction

Healthcare regulations are a dynamic and ever-changing field requiring organizations to commit diligent resources to stay apprised and compliant -- an important aspect for a public reputation of providing safe, high quality patient care. Healthcare is not a unique industry in this regard -- other industries are also highly regulated, and like these other industries, there is an opportunity for staff to have a specialized knowledge and skill set that focuses specifically on regulatory compliance. The titles of these specialized professionals may vary, but large organizations often have personnel titles or department names such as compliance, regulatory affairs, accreditation and regulations, or licensing. Smaller organizations will likely have an integrated approach to this work, where the quality or administration departments and operational leaders assume this responsibility. Alternatively, organizations can also outsource or purchase consultation services in this area.

Regulatory professions are accountable for ensuring ongoing compliance with all of the laws and regulations that pertain to their business. This includes working with federal, state, and/or local regulatory agencies on specific requirements for their unique business line. For example, the requirements for an outpatient medical practice will be different than those of an outpatient ambulatory surgery center; a critical access hospital, rehabilitation hospital, psychiatric hospital, and a general acute care hospital will have different requirements; and home care and hospice agencies will have different requirements than medical homes or accountable care organizations. Advising organizations on a multitude of requirements and helping these organizations ensure sustained compliance is a vital role in an organization to ensure patient safety.

This module is divided into three sections to help healthcare professionals understand the
overarching structure for organizational compliance. The first section focuses on regulation, the second section focuses on accreditation and certification, and the third section brings together the program infrastructure for continuous regulatory and accreditation readiness.

**Regulation**

**Federal Regulation**

The healthcare industry is regulated by all levels of governmental agencies – federal, state, and local, making it challenging for quality professionals to feel confident that they have an understanding of regulatory oversight. A simple internet search on “healthcare regulation” yields 72,800,000 citations – an overwhelming place to start! Healthcare regulations create an environment where quality professionals spend inordinate amounts of time responding to changing rules while continuing to demonstrate compliance with difficult existing rules. In a dynamic market place, healthcare executives are driven to expand and refine the services offered to meet the needs of the community or the organization--creating the ongoing need for quality professionals to research regulations and interpret the application to the organization’s new or unique situation.

**Federal regulatory agencies.** There are a number of federal agencies that healthcare regulatory professionals will become familiar with.

**Occupational Safety and Health Administration.** The United States Department of Labor’s Occupational Safety and Health Administration (OSHA) is an agency healthcare professionals will be familiar no matter where in the healthcare continuum services are provided (www.osha.gov). OSHA was created by Congress with the Occupational Safety and Health Act of 1970, to assure safe working conditions. This agency is positioned to be visible within the governmental structures as OSHA's administrator answers to the Secretary of Labor, who is a member of the cabinet of the President of the United States.
Department of Health and Human Services. The Department of Health and Human Services (HHS) describes their role as being the principal agency for protecting the health of Americans and providing essential human services for those who are least able to help themselves (www.hhs.gov). A huge governmental agency with over 300 services, HHS is divided into the following operating divisions to administer the services that impact healthcare regulations:

- Administration for Children and Families (ACF)
- Administration on Children, Youth and Families (ACYF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- National Cancer Institute (NCI)
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Healthcare quality professionals will deal with different operating divisions depending on the segment of healthcare where they are employed, however, most will become familiar with several key divisions. The most common divisions to be familiar with are the Centers for Medicare and Medicaid, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Agency for Healthcare Research and Quality.

The Centers for Medicare and Medicaid (CMS) was founded in 1965 to oversee most of the regulations related directly to the healthcare system (www.cms.hhs.gov). What becomes confusing for healthcare organizations, is that CMS also provides government-subsidized medical coverage through a number of programs: Medicare for the elderly and disabled; Medicaid for lower-income individuals and families; and State Children’s Health Insurance Program (SCHIP) for health insurance coverage for children under 19. Therefore, in addition to
being a regulator, Medicare and Medicaid together provide healthcare insurance for one in four Americans making the Medicare program the nation’s largest health insurer handling more than 1 billion claims per year (www.hhs.gov accessed 3/5/12). HHS works closely with state and local governments, and because many HHS-funded services are provided by State or County agencies, or through private sector grantees, it may be difficult for healthcare professionals to tease out the Federal role in regulation versus as an insurer, and the State role acting on behalf of the Federal programs!

Amongst the many federal laws and regulations that CMS oversees, which healthcare professionals will want to become familiar with, are the following three: Clinical Laboratory Improvement Amendments, Health Insurance Portability and Accountability Act, and Emergency Treatment and Active Labor Act.

- The Clinical Laboratory Improvement Amendments (CLIA) of 1988 established quality standards for all laboratories (regardless of where the test was performed) to ensure the accuracy, reliability, and timeliness of patient test results. CLIA regulations are stratified based on the complexity of the test method: waived complexity; moderate complexity, including the subcategory of provider-performed microscopy; and high complexity. The regulations specify quality standards for laboratories performing moderate and/or high complexity tests, and require waived laboratories to enroll in CLIA and follow manufacturers’ instructions (www.cms.hhs.gov/clia).

- The Health Insurance Portability and Accountability Act (HIPAA) provides federal protections for personal health information and provides patients with rights (www.hhs.gov/ocr/privacy).

- The Emergency Treatment and Active Labor Act (EMTALA) requires Medicare-
participating hospitals to provide emergency room patients with a full medical screening regardless of ability to pay, and to refrain from transferring them until they have been stabilized (www.cms.gov/EMTALA).

The Centers for Disease Control and Prevention (CDC) examines public health and possible health threats from infectious diseases (www.cdc.gov). The CDC also monitors birth defects, disabilities, diseases and conditions, emergency preparedness and response, environmental health, genetics and genomics, health promotion, injury and violence, travelers’ health, vaccines and immunizations and workplace safety and health.

The Food and Drug Administration (FDA) is the regulatory agency responsible for the controlling the safety and effectiveness of the drug supply. The FDA also regulates food safety, biologics and the national blood supply, medical devices, and product recalls (www.fda.gov).

The Agency for Healthcare Research and Quality (AHRQ) conducts research aimed at improving the quality of healthcare, reducing its costs, and addressing patient safety and medical errors (www.ahrq.gov). AHRQ is different from the regulatory agencies in that healthcare professionals will identify AHRQ as a resource rather than a regulatory agency, for emerging evidence for the provision of care, performance metrics, or evaluation data.

Federal data systems have also been established to assist healthcare organizations in their due diligence requirements to determine qualifications of practitioners, providers, and suppliers across state lines. Healthcare professionals should be familiar with two key systems, the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank (www.npdb-hipdb.hrsa.gov). Table 1 provides a side-by-side comparison to explicate the information available and to whom. These data banks were established with strict confidentiality protections and the HHS OIG has the authority to impose civil money penalties.
on those who violate the confidentiality provisions (Title IV of Public Law 99-660, [www.npdb-hipdb.hrsa.gov/resources/titleIv.jsp](http://www.npdb-hipdb.hrsa.gov/resources/titleIv.jsp)).

(insert Table 1)

The National Practitioner Data Bank (NPDB) was established in 1987 by authorizing the government to collect information concerning sanctions against healthcare practitioners and entities that were taken by state licensing authorities. In 1990 Congress amended the law to broaden the language that included any negative action or finding by these authorities, not just sanctions. Intended to improve the quality of healthcare, this law encourages state licensing boards, hospitals, professional societies, and healthcare organizations to identify and discipline those who engage in unprofessional behavior; to report medical malpractice payments; and to restrict the ability of incompetent physicians, dentists, and other healthcare practitioners to move between states without disclosure or discovery of their previous history. Examples of adverse actions can involve licensure, clinical privileges, professional society membership, and exclusions from Medicare and Medicaid. Governmental Peer Review Organizations and private accreditation organizations must also report negative actions taken against healthcare practitioners or organizations.

The Healthcare Integrity and Protection Data Bank (HIPDB) was also created to combat fraud and abuse in health insurance and healthcare delivery. The HIPDB is a national data collection program for the reporting and disclosure of certain final adverse actions taken against healthcare practitioners, providers, and suppliers. The HIPDB collects information regarding licensure and certification actions, exclusions from participation in Federal and State healthcare programs, healthcare-related criminal convictions and civil judgments, and other adjudicated actions or decisions as specified in regulation. Acting through the Office of Inspector General
(OIG) and the U.S. Attorney General, HIPDB was created by the Health Insurance Portability and Accountability Act of 1996, Section 221(a), Public Law 104-191.

Leadership for the HHS operating divisions is divided into geographic regional offices – these are the offices that regulatory professionals deal with directly. Healthcare quality professionals will need to be familiar with the names and contact information for staff in their geographic offices (Table 2).

*(Insert Table 2)*

**Federal regulation resources.** Finding information about federal regulations has become progressively easier as the government has invested in publically available electronic databases accessed through the internet. The Federal Register is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as presidential executive orders ([www.gpoaccess.gov/fr/](http://www.gpoaccess.gov/fr/)). The Code of Federal Regulations (CFR) is the codification of these rules published in the Federal Register, which is divided into 50 titles that represent broad areas subject to federal regulation. It is updated by amendments that appear daily in the Federal Register and each volume of the CFR is updated once each calendar year.


Twice a year Federal agencies publish a Regulatory Agenda ([http://resources.regulations.gov/public/component/main?main=UnifiedAgenda](http://resources.regulations.gov/public/component/main?main=UnifiedAgenda)). This agenda can be very helpful for healthcare organizations to understand the direction for the agency in the coming year. As an example, the HHS plan provides not only the annual priorities for the fiscal year as an overview, but also provides detailed information about each of the priorities (the priority; if it is an unfunded mandate; legal authority; statement of need; legal basis; alternatives; costs and benefits; risks; timetable; and contact information). These documents are useful
communication tools for regulatory professionals to understand future direction for regulations.

The process to change regulations can be slow and frustrating with resulting outdated regulations. Conway and Berwick (2011) recently outlined the challenges of evidence based regulatory standards and the process to keep them current. Governmental regulators must provide due process to those affected by their actions -- this provides the healthcare industry the opportunity to review proposed changes with any known supporting evidence, and the opportunity to provide written feedback or testimony prior to changes in the regulation. As an example, the CMS Conditions of Participation (CoP) were last systematically updated in 1986. However, in the President’s Executive Order 13563 (January 18, 2011) titled Improving Regulation and Regulatory Review, the President recognized the importance of a streamlined regulatory framework (www.hhs.gov/open/execorders/13563/index.html). Citing that unnecessary and duplicative regulations could damage the market economy by imposing unnecessary costs on the private sector and citizens, the President directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations -- to identify rules that could be (a) eliminated as obsolete, unnecessary, burdensome, or counterproductive; or (b) that could be modified to be more effective, efficient, flexible, and streamlined. As a result of this Executive Order, in late 2011, CMS proposed CoP revisions in 3 areas prioritized due to morbidity, mortality, and increased costs – transitions from the hospital, patient-centered care, and quality improvement programs. Two of the proposed rules published are expected to result in savings to the health industry of as much as $5 billion over five years.

The benefit of regulations compared to the costs may also not always be clear. Cato Institute published a study that determined regulation provided benefits in the amount of $170 billion but cost the public up to $340 billion (Conover, 2004)! The majority of the cost was
attributed to be from medical malpractice, FDA regulations, and facilities regulations.

**Federal role in quality healthcare.** The Social Security Act mandates the establishment of minimum health and safety standards that must be met by providers and suppliers participating in the Medicare and Medicaid programs (www.cms.hhs.gov/Regulations-and-Guidance/Regulations-and-Guidance.html). In 1935 the Social Security Act was signed by President Roosevelt to provide benefits for retirees and the unemployed. This was amended in 1965, signed by President Johnson, to create the Medicare and Medicaid programs. Medicare, as a federal insurance program, provides a wide range of benefits for most people over age 65, Social Security beneficiaries under age 65 entitled to disability benefits, and individuals needing renal dialysis or renal transplantation. The care is provided through “providers and suppliers” that participate in the Medicare program by providing care and receiving reimbursement from Medicare. Providers, in Medicare terminology, include patient care institutions such as hospitals, critical access hospitals, hospices, nursing homes, and home health agencies. Suppliers are agencies for diagnosis and therapy rather than sustained patient care, such as laboratories, clinics, and ambulatory surgery centers. The providers and suppliers are subject to federal healthcare quality standards – thus the Federal government has a large role in setting quality standards and oversight of compliance to these standards for Medicare beneficiaries.

CMS developed Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that healthcare organizations must meet in order to participate in the Medicare and Medicaid programs and receive reimbursement for services (www.cms.gov/CFCsAndCoPs). These standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CoPs and CfCs apply to the following healthcare organizations:

- Ambulatory Surgical Centers (ASCs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
• Critical Access Hospitals (CAHs)
• End-Stage Renal Disease Facilities (ESRD)
• Federally Qualified Health Centers
• Home Health Agencies
• Hospices
• Hospitals
• Hospital Swing Beds
• Intermediate Care Facilities for Persons with Mental Retardation (ICF/MR)
• Organ Procurement Organizations (OPOs)
• Portable X-Ray Suppliers
• Programs for All-Inclusive Care for the Elderly Organizations (PACE)
• Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
• Psychiatric Hospitals
• Religious Nonmedical Healthcare Institutions
• Rural Health Clinics
• Long Term Care Facilities
• Transplant Centers

(Insert table 3)

Although each program’s CoP or CfC will be different, the table of contents from the hospital program (Table 3) provides an example to gain insight into the kinds of regulations found in the CoP and how they are organized (Code of Federal Regulations, Title 42, Volume 3, Part 482). These federal quality standards are organized in State Operations Manuals (SOM) as Conditions—with subsidiary Standards under each Condition. There are individual sets of Conditions or Requirements for each type of provider or supplier subject to certification (as listed above). The Condition or Requirement in the SOM is expressed in a summary paragraph which describes the quality or result of operations to which all the subsidiary standards are directed. An excerpted example of this organization is from the hospital CoP as follows:

§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program
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.

§482.21(a) Standard: Program Scope
§482.21(b) Standard: Program Data
§482.21(c) Standard: Program Activities
§482.21(d) Standard: Performance Improvement Projects
§482.21(e) Standard: Executive Responsibilities

The CMS regional offices have been delegated the authority by the Secretary for assuring that healthcare providers and suppliers participating in the Medicare, Medicaid, and CLIA programs meet applicable Federal requirements. CMS regional offices use State health agencies to determine whether healthcare entities meet Federal standards. This process is called certification.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions: (a) Survey and make recommendations regarding the issues listed in §488.10. (b) Conduct validation surveys of accredited facilities as provided in §488.7. (c) Perform other surveys and carry out other appropriate activities and certify their findings to CMS. (d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with §489.13 of this chapter.

The State agencies used to evaluate healthcare entities are usually the same agency responsible for State licensing, however they are reimbursed with federal funds for this work. There are also provisions for CMS approved accreditation bodies to determine if healthcare entities meet the Medicare CoPs -- these providers are referred to as deemed status providers for participation (also known as the deeming process) (see Appendix 1). Therefore, CMS certified healthcare entities can receive a visit from Federal, State, or accreditation agencies to evaluate Federal standards for certification or recertification, for complaint investigations, or as part of
random validation programs to confirm survey findings as valid and reliable. In an effort to assure evaluations are done in a consistent manner by all of these agencies, the SOM are published and available publically.

The survey process will vary depending on the services under review and may vary slightly depending on individual state resources such as the staff or disciplines available to conduct surveys. During a survey, surveyors (healthcare professionals) determine if each standard is met by conducting document review, interviews with staff and leaders, and observation of routine procedures and patient care. After a CMS survey, the State agency (acting as CMS surveyors) prepare a certification report for the CMS regional office and sends the healthcare organization a Statement of Deficiencies (Form CMS-2567). The healthcare organization is given 10 calendar days to respond to CMS with a Plan of Correction (PoC) for each cited deficiency on the same Form 2567. Once the PoC is accepted by CMS, it is ultimately made available publically through the Freedom of Information Act. While an organization may fail to comply with one or more of the subsidiary standards during any given survey, it cannot participate in Medicare unless it meets each and every Condition. If the healthcare organization does not come into compliance with all Conditions within the time period accepted as reasonable by CMS, they are certified as “noncompliant” and a termination process begins for the Medicare and Medicaid programs. Termination means that the healthcare entity cannot receive Federal reimbursement for services – a financial loss for organizations.

Immediate Jeopardy is a mechanism to escalate “crisis” survey issues immediately within both the State and Federal agencies and with the healthcare provider (CMS, 2004). Immediate Jeopardy (IJ) is determined when a crisis situation is identified where the health and safety of individual(s) are at risk. IJ applies to all certified Medicare/Medicaid entities except CLIA, and
to all types of surveys and investigations (certification, recertification, revisits, and complaint investigations). IJ is defined as a situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death. Appendix 2 provides the IJ triggers from the CMS guidelines. Only one individual needs to be at risk, and serious harm does not have to occur before considering an IJ—the potential for the outcome can also constitute IJ. Harm may also have occurred in the past, present, or likely to occur in the future because the organization either created a situation or allowed a situation to continue and had an opportunity to implement corrective or preventive measures. Once IJ is considered, the investigation continues until it is confirmed or ruled out.

The entire survey team is involved in the investigation to address three components for the consensus decision process – harm, immediacy, and culpability. When IJ has been determined, the survey team leader will notify the organization administrator prior to leaving the premises. The organization will need to immediately begin corrective actions to resolve the IJ situation. Resolution and removal of the IJ is determined only through on-site survey (either at the time the IJ is called or a follow-up survey). If the IJ is not resolved, termination procedures are initiated.

For organizations with complex large-scale issues that can not be resolved quickly, CMS also has a process to contract with the hospital, a Systems Improvement Agreement, for CMS-approved consultants to provide external ongoing monitoring and oversight of the improvement process and to assist the organization to prepare for a full CMS survey.

In addition to conducting compliance surveys, CMS contracts with one organization in each state (plus the District of Columbia, Puerto Rico, and the U.S. Virgin Islands) to serve as the Quality Improvement Organization (QIO) contractor to guide performance improvement and efficiency programs (www.cms.gov/QualityImprovementOrgs). QIO contracts are 3-year
contracts with each contract cycle referenced as a statement of work (SOW). QIOs are private, mostly not-for-profit organizations, which are staffed by healthcare professionals who are trained to review medical care and help beneficiaries with complaints about the quality of care. By law, the mission of the QIO Program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. CMS identifies the core functions of the QIO Program as: Improving quality of care for beneficiaries; Protecting the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting; and Protecting beneficiaries by expeditiously addressing individual complaints. CMS is required to publish a Report to Congress every fiscal year that outlines the administration, cost, and impact of the QIO Program.

CMS progressively publishes more and more healthcare performance data for public information. The Quality Care Finder website (www.cms.gov/center/quality.asp) includes data on hospitals, nursing homes, home health agencies, ambulatory surgical centers, dialysis centers, physicians, and Medicare plans allowing the public to compare and contrast performance on a number of metrics. The reporting methodology varies from simple plus or minus signs to reporting actual performance scores. Although these data are publically available, it can be challenging for consumers to sift through multiple metrics and interpret the information to make informed decisions.

State Regulators

State governments maintain State health departments that operate licensing programs for healthcare providers and organizations. Licensing requires organizations, providers or practitioners to meet legal requirements to practice or provide services. In addition to providing licensing services, these departments usually operate enforcement programs for both State
licensing requirements and for Federal certification requirements. Local governments, such as counties and municipalities, can also have their own health departments (which may be branches of the State health department). Licensure for practitioners may be part of State departments of health or separate entities who are accountable for disciplinary investigations and actions.

State regulations vary greatly in content, detail, and organization of regulations. This requires regulatory professionals to have state-specific knowledge to guide organizations within a given state. Corporate systems that operate in multiple states depend on regulatory professionals who play a critical role to navigate requirements within each state. As an example of state variation, performance improvement requirements for hospital programs in New York, Wisconsin, and California are excerpted in Tables 4, 5, 6 and 7 in reference to federal requirements. Federal CMS CoP §482.21 for quality assessment and performance improvement has 5 standards which detail requirements that 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. In New York, Administrative Code for the Department of Health (Table 4) sets very detailed prescriptive regulations for hospital quality assurance programs, that describe who, what, how often, etc.. In contrast, Wisconsin Administrative Code for the Department of Health and Family Services (Table 5) assigns program accountability to the chief executive officer and chief of the medical staff and provides a broad overview of requirements for an efficient and effective program. California regulations, however, look very different from both New York and
Wisconsin. California regulations do not duplicate Federal requirements but supplement federal expectations in both Administrative Code -- for broad requirements of the medical staff to oversee the quality of care provided (Table 6); and in Health and Safety Code, where specific detailed patient safety program requirements are outlined (Table 7).

(Insert Tables 4, 5, 6 & 7)

State healthcare surveys appear much like federal surveys and likely are the same personnel performing the survey. State regulators survey healthcare organizations for licensure, enforcement of regulations, and in response to complaints made to the agency by consumers of the healthcare service, their family members, or concerned staff. Licensure visits may be routine inspections within defined time periods, or may be random unannounced visits based on the resources available to the state agency. State laws may dictate reporting requirements of licensed organizations for unusual occurrences or adverse events, and the law may require the state agency to investigate certain self-reports within a given timeframe. Discretion may be allowed on how the agencies respond and investigate complaints based on the nature of the complaint and the severity of the allegation. As with federal surveys, state agencies provide organizations with deficiency reports and require written responses (corrective actions) within a defined time period. Many states use the Federal Form 2567 for this purpose. If organizations are not able to become compliant with state regulations, they risk loss of licensure within the state and the inability to provide healthcare services. State laws may also allow for Immediate Jeopardy determinations similar to the CMS IJ process. Reports of investigations and the organizations’ response to citations may also become public information.

State laws may require public reporting of performance data by licensed healthcare providers. Minimum data sets, healthcare outcomes for defined diagnostic groups, healthcare
acquired infections, adverse events (or never events), actions taken against licensed medical staff or other providers, employee injuries, and financial data are common performance metrics that may be public information within a state. Reporting requirements vary on a state-by-state basis, however the national trend is for increased reporting and public transparency.

**Health Plan Regulators**

Regulation of health plans and insurance is difficult to understand and is best described by documents from the Library of Congress Congressional Research Service (1997). Healthcare professionals working with health plans will want to understand the regulations specific to their situation in the state the services are provided. The federal government regulates managed care and other health plans sponsored by the private-sector. However, the states regulate the business of insurance, which includes the managed care organizations (MCO) such as a health maintenance organizations (HMO) that offer managed care policies to individuals, employers, or other purchasers. To add to the complexity, if a private sector employer sponsors a plan that is not purchased from an MCO (i.e., the plan is self-insured), then the plan is regulated solely by the federal government. If that employer contracts with an MCO to provide managed care services to employees, then the regulation depends on who bears the risk: if it is the MCO, the plan is regulated by the state; if the risk is borne to any degree by the employer, then the plan is subject to federal law only!

This complex division of regulatory responsibilities between the federal and state governments resulted from provisions of several federal laws and subsequent decisions of federal courts. The Employee Retirement Income Security Act of 1974 (ERISA) preempted the states from regulating health plans of private sector employers but left to the states the regulation of the business of insurance. While the HMO Act of 1973 established certain federal
standards for HMOs that elected to operate under federal law, almost all other regulatory authority over the business of health insurance remained with the states. This deferral to state regulation of insurers was altered with the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) which applied federal minimum requirements to state-regulated insurers as well as to employer-sponsored plans, including managed care plans.

Managed care regulations vary state by state, although many states have laws and regulations based on the National Association of Insurance Commissioner’s (NAIC) HMO Model Act. NAIC published model laws on quality assessment and improvement, provider credentialing, network adequacy, grievance procedures, and standards for utilization review. An example of state regulations that have been developed is in the California Code of Regulations which established the Department of Managed Health Care to specifically regulate and enforce regulation for managed care (www.dmhc.ca.gov or http://www.hmohelp.ca.gov).

Private Regulators

Although regulation is primarily a governmental role, there are also private regulators in healthcare. Field (2007) provides a rich historical perspective on regulation in healthcare, as well as an introduction to private regulators. The American Medical Association (AMA) may be the most well-known private regulator. The AMA sponsored creation of organizations with oversight roles for the medical profession which supplement governmental regulators, such as organizations that accredit medical schools, administer licensure examinations, and certify specialists. State medical boards, for example, use privately administered examinations in granting medical licenses, and the Medicare program relies on specialty certification as an indicator of physician quality.
Accreditation

Accreditation and certification are terms used in many organized industries in the United States, including healthcare. The terms are often used incorrectly or interchangeable which creates confusion, plus they can be used differently in various segments of the industry. The Merriam-Webster dictionary defines accreditation as official authorization or approval, or recognition for conforming to standards, or to recognize as outstanding; while certification is defined as recognition for meeting special qualifications within a field (www.merriam-webster.com/dictionary). In healthcare, accreditation commonly refers to a process that reviews an entire organization’s operations while certification commonly refers to a review of part of the organization’s operations or a specific population provided care. But certification may also be a reference to an individual’s competency or the determination of an organization’s eligibility to participate in a government program. Accreditation is granted by private sector organizations (trade associations, professional societies, or independent businesses) while certification can be provided by either private sector organizations or governmental agencies. For simplicity, the term accreditation will be used generically throughout this module to refer to both accreditation or certification activities.

Healthcare Accreditation

In the healthcare industry, the act of accreditation involves an objective or impartial review of an organization by an external agency¹ against recognized and published standards or requirements. This impartial accreditation review is conducted by industry professionals (i.e. physicians, nurses, pharmacists, dieticians, administrators, life safety code specialists, etc.) who, through written reports, publicly attest to the resulting accreditation status. The review is

¹ “Agency” is used as a generic term to represent accreditation organizations or bodies, or certification organizations or bodies.
“voluntary” as compared to “required” like licensure, however, the review may be required in order to participate in reimbursement programs such as Medicare or for participation in contracts to provide care and receive reimbursement through insurance programs. In competitive markets, accreditation or certification may be viewed by the public as an endorsement for providing a minimum level of quality or standard of care, therefore a business “requirement” even if it is “voluntary.”

Accreditation may also be accepted as evidence of meeting State and Federal requirements. The CMS deeming process was discussed earlier in this module where accredited organizations would be deemed to meet CMS CoP requirements when accredited through CMS approved agencies (see Appendix 1). Deemed status is attractive to many organizations as it negates the need for an additional survey by State personnel on behalf of Federal CMS regional offices. In addition, some states accept accreditation to meet regulatory requirements for state licensure. An example of this would be the Consolidated Hospital Survey Program found in the California Health and Safety Code (http://law.onecle.com/california/health/1282.html). California hospitals experience a combined state licensing and accreditation survey with three contracting parties - The Joint Commission (accrediting agency), The Institute for Medical Quality (IMQ) a subsidiary of the California Medical Association (CMA), and the California Department of Public Health (CDPH). Surveyors from each organization survey against Federal law for CoP compliance, State law for licensing review, and/or accreditation standards for accreditation decisions. This combined survey also provides for Medicare certification through deeming.

Federal certification requirements are found across the healthcare continuum. For example, a Federal certification requirement is CMS’s regulation for all laboratory testing
performed on humans through the Clinical Laboratory Improvement Amendments (CLIA; www.cms.hhs.gov/clia). All clinical laboratories must be certified to receive Medicare or Medicaid payments. CLIA has a list of CMS-approved accrediting organizations that may perform laboratory inspections, whose requirements are deemed as being equivalent to or more stringent than CMS’s regulatory requirements (CMS accepts the accrediting organization’s inspection in lieu of its own inspection). Another Federal certification requirements is found in the Mammography Quality Standards Act (MQSA) which requires that all facilities providing mammography must be certified by the FDA (www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm110906.htm). To be certified, a facility must be accredited and the FDA designates the acceptable accrediting bodies.

While the majority of hospitals and many health plans are accredited, accreditation has not been uniformly adopted across all segments of the healthcare industry. Home care and hospice agencies, one of the fastest growing segments of the continuum, may also be accredited – The Joint Commission (2011) states on their website that 6000 agencies are accredited, and Community Health Accreditation Program (2011) websites states 5000 agencies are accredited with them. Nursing home accreditation has been limited, perhaps because there have not been the same financial incentives to seek accreditation as legislation does not authorize deemed status in Medicare or Medicaid for private accrediting bodies to substitute for governmental oversight. CMS (Medicare and Medicaid) and the states (Medicaid) have developed regulatory standards and government survey and certification programs to enforce nursing home regulations. Ambulatory care has yet to adopt accreditation as an industry standard. Few insurance or program participation requirements require accreditation even though the National
Center for Healthcare Statistics (2010) reported 1.2 billion visits annually (averaging 4 visits per person) accounting for 21.2% of 2008 healthcare expenditures.

**Examples of Accreditation Agencies.** Accreditation agencies have grown rapidly in the last decade and now represent a significant segment of the healthcare industry. Not only have the number of organizations that offer services grown, but the services provided have also expanded. Agencies no longer offer one program as their single service line, but have diversified to work across the healthcare continuum with both accreditation and certification programs, and most also offer associated education or consultation programs to assist organizations with survey readiness activities. A number of common agencies are summarized alphabetically below with an overview of the services they describe as offering. Healthcare quality professionals are encouraged to explore agency websites to better understand the agencies that accredit or certify their own organizations to learn specific information about these programs. Many of the organizations provide tools or resources on their websites to help consumers understand or evaluate compliance or quality of care when considering the services of an organization. Healthcare providers or other industry organizations may also find assessment or evaluation tools made available by these agencies, in their effort to improve the quality and safety of care across the industry.

**AABB.** Formerly the American Association of Blood Banks, AABB accreditation is granted for collection, processing, testing, distribution, and administration of blood and blood components; hematopoietic progenitor cell activities; cord blood activities; perioperative activities; relationship testing activities; immunohematology reference laboratories and specialist in blood bank technology schools (www.aabb.org/sa).

**Accrediting Association for Ambulatory Healthcare (AAAHC).** Developed specifically for the ambulatory healthcare market segment, AAAHC accreditation programs are
specific to managed care organizations, office-based surgery centers, and ambulatory
healthcare organizations such as the following: ambulatory healthcare clinics; ambulatory
surgery centers; birthing centers; college and university health centers; community health
centers; dental group practices; diagnostic and other imaging centers; Indian health centers;
lithotripsy centers; military healthcare facilities; multi- and single-specialty group practices;
occupational health centers; office-based anesthesia organizations; office-based surgery centers
and practices; oral and maxillofacial surgery practices; pain management centers; podiatry
practices; radiation oncology centers; urgent or immediate care centers; and women's health
centers (www.aaahc.org).

**Accreditation Commission for Healthcare (ACHC).** Accreditation and deeming
authority is offered for Home Health, Hospice, and DMEPOS (Durable Medical Equipment,
Prosthetics, Orthotics, and Supplies) and accreditation programs are offered for Specialty
Pharmacy, Women's Post-Breast Surgery Fitter Services, Medical Supply Provider Services, and
Complex Rehab & Assistive Technology Supplier (www.achc.org).

**American College of Radiology (ARC).** Accreditation programs are offered in the
following areas: Breast MRI, Breast Ultrasound, CT, Mammography, MRI, Nuclear
Medicine and PET, Radiation Oncology, Stereotactic Breast Biopsy, and Ultrasound
(www.acr.org/accreditation).

**College of American Pathologists (CAP).** In addition to general laboratory accreditation,
CAP also provides specialty programs for reproductive laboratories and forensic urine drug-
testing programs (www.cap.org).

**Commission of Office Laboratory Accreditation (COLA).** COLA accredits physician
office laboratories, hospitals, and independent laboratories for CLIA compliance (www.cola.org).
Commission on Accreditation of Rehabilitation Facilities, International (CARF). Accreditation programs are offered in the following areas across the healthcare continuum: Aging Services, Behavioral Health, Opioid Treatment Programs, Business and Services Management Networks, Child and Youth Services, Employment and Community Services, Vision Rehabilitation, Medical Rehabilitation, and DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) (www.carf.org).

Community Health Accreditation Program (CHAP). CHAP has CMS deeming authority to accredit agencies providing home health, hospice, and home medical equipment services (www.chapinc.org).


National Committee for Quality Assurance (NCQA). NCQA accredits the following types of programs: managed care organizations; managed behavioral healthcare organizations; preferred provider organizations; disease management; new health plans; VA human research protection accreditation program; partnership for human research protection accreditation program; and interactive survey system overview. NCQA certifies the following programs: credentials verification organization; physician organization; utilization management and credentialing; disease management; privacy certification for business associates; and interactive
survey system overview (www.ncqa.org).

**The Joint Commission (TJC).** TJC accredits the following types of healthcare organizations: hospitals; healthcare networks (managed care plans, preferred provider organizations, integrated delivery networks, and managed behavioral health); home healthcare organizations (home health, hospice, home infusion, durable medical equipment, personal care and support); nursing homes and other long-term care facilities; assisted living facilities; behavioral healthcare organizations; ambulatory care providers; and clinical laboratories. It certifies the following types of programs: disease-specific care, healthcare staffing, lung volume reduction surgery, and left ventricular assist device implantation (www.jointcommission.org).

**URAC.** Formerly known as the Utilization Review Accreditation Commission, URAC also is known by a second corporate name, the American Accreditation HealthCare Commission. The following accreditation programs are offered: case management, claims processing, consumer-directed health, core accreditation, credentials verification organization, disease management, health call center, health network, health plan, health provider credentialing, health utilization management, health website, Health Insurance Portability and Accountability Act (HIPAA) privacy, HIPAA security, independent review, and workers’ compensation utilization management (www.urac.org).

**The Accreditation Process**

Similar to regulatory requirements or standards, accreditation and certification standards are published or available to organizations submitting an application for review. These standards are developed based on evidence for practice, expert opinion and consensus, or research. Those wishing to provide CMS deemed status are pre-approved by CMS to assure their minimum standards meet or exceed the CoP of CfC. The requirements or standards that are not tied to the
CMS requirements evolve over time as knowledge and technology change in the industry and are more responsive with changes than governmental regulations. Standards may focus on the infrastructure of the organization, the processes of care delivery, or the outcomes of the care delivery system.

The review cycle varies with each accreditation agency, however many are 2- or 3-year cycles. Cycles begin with an application requesting an initial or follow-up review or re-accreditation. The accrediting agency reviews the application to determine the scope of the review by evaluating the size and scope of the organization and services to be reviewed. Historically a paper-based process, the accreditation industry has shifted to more electronic review in advance of on-site survey activity, leveraging technology to securely transport large volumes of confidential patient and organizational information.

Performance measures are often a required element of accreditation. Measures may be developed by the review organization, by professional organizations through consensus, or through national organizations such as the National Quality Forum (NQF) (www.qualityforum.org). NQF is recognized as a voluntary consensus standards-setting organization under the National Technology Transfer and Advancement Act of 1995. The NQF portfolio of measures is constantly evolving with approximately 700 measures in 2012. By using a formal definition of consensus from the Office of Management and Budget, NQF-endorsed measures have special legal standing for Federal agencies to adopt. The 2012 NQF Report to Congress, Changing Healthcare by the Numbers, states that about 85 percent of measures in Federal health programs are NQF-endorsed, including those that apply to hospitals, clinicians, nursing homes, patient-centered medical homes, and many other settings. These performance measures are used for required public performance reporting, value-based purchasing by
governmental agencies or insurance programs, and are often also used by accreditation agencies to judge quality. Performance measurement may be an ongoing review for accreditation with quarterly or annual performance ratings that may be included in public websites. For example, in the hospital industry, TJC was one of the first accreditation agencies to include on their public website not only the organization’s accreditation status but also comparative performance with respect to national patient safety goals and to quality goals based on their own required data (i.e., for acute myocardial infarction, heart failure, community-acquired pneumonia, pregnancy and related conditions, surgical infections, and childhood asthma care). In the health plan industry, NCQA reports its accreditation decisions on their public website and also includes plan-specific information about performance on Healthcare Effectiveness and Data Information Set (HEDIS) grouped in five consumer-friendly categories (Access and Service, Qualified Providers, Staying Healthy, Getting Better, and Living with Illness).

On-site accreditation surveys are completed by professionals from within the field of review. The length of the review is dependent on the size of the organization and the complexity of services offered. In addition to document review (reports, management plans, risk assessments and evaluations, etc.), which may have taken place in advance of the on-site review, interviews with staff, patients, and providers are a normal part of a survey. Depending on the healthcare services under review, on-site surveys will also encompass observations of routine care delivery and the associated medical record documentation, staff performing procedures, and visits to homecare patients. Most reviews conclude with a summation conference by the review team to inform leadership of compliance findings. A report of the findings may be left upon the review team’s exit or provided to the organization at a later date electronically.
Following review of all the data sources, an accreditation decision is determined for the organization. The decision usually includes an overall assessment of the organization or service that reflects a full accreditation decision or a decision with limitations or restrictions that the organization must resolve within a designated timeframe. Cited deficiencies or requirements for improvement must be corrected and documentation submitted to the reviewing organization within predetermined timeframes. The organization’s leaders often receive in-depth information that can be used internally to prioritize performance improvement activities to improve care quality and patient safety, with the implicit expectation that the organization will use this feedback in their improvement programs. The accreditation decision is also shared with interested parties such as consumers, patients, purchasers, and government agencies that require accreditation or certification for participation. The level of detail shared outside the organization ranges from a simple list of organizations that were successful (with no indication of organizations that failed) to detailed information on performance.

In an effort to have the accreditation review be an ongoing process, accreditation agencies may require intra-cycle activities to confirm sustained compliance. Requirements for a periodic self-assessment or performance review between surveys may require submission of data to the agency or for public reporting or attestations of process completion.

Accreditation comes at significant cost to an organization. Not only are human resources required for the preparation and attention to the details of the required standards, fees are associated with the accreditation process. Fees often are on a sliding scale that reflects the size and complexity of the organization, and for on-site surveys, the number of surveyor hours or days required for the review. There are often annual participation fees as well. Costs for survey preparation, hosting the survey team for the on-site survey process, intra-cycle monitoring, and
fees assessed for the regular survey cycle are also factors considered as organizations choose an accreditation agency. Because these fees can be substantial, they must also be included in operating budgets.

**Accreditation Value**

As the healthcare industry faces ongoing pressure for cost containment, questions surface as to the “value” of accreditation in relation to the cost. The healthcare literature is beginning to provide evidence to supplement the historical anecdotal perspective that accredited organizations have made a public proclamation that they were providing the infrastructure for quality patient care. The most extensive review of accreditation value was a literature review published by Accreditation Canada (2011). These authors reported that accreditation was an integral part of healthcare services in over 70 countries, as either a voluntary or governmental mandated requirement, and cited a number of benefits which have been clustered below into groups of benefits.

**External Credibility.** Consistent with the historical view in the United States, accreditation was cited as improving the organization’s reputation among end-users and enhancing their awareness and perception of quality care. Accreditation was also cited as improving communication and collaboration internally and with external stakeholders. All of this was thought to demonstrate credibility and a commitment to quality and accountability.

**Improved Quality.** Of great importance externally to the organization, accreditation was cited as leading to improved patient outcomes. The improved outcomes may be the result of accreditation providing a framework to help create and implement systems and processes that improve operational effectiveness. It was also
cited as providing healthcare organizations with a well-defined vision for sustainable quality improvement initiatives. This vision and framework enabled organizations to sustain improvements in quality and organizational performance; enabled on-going self-analysis of performance in relation to standards; and ensured an acceptable level of quality among healthcare providers. These quality improvements were realized as the accreditation process increased healthcare organizations’ compliance with quality and safety standards; decreased variance in practice among healthcare providers and decision-makers; codified organizational policies and procedures; and continuously raised the bar with regard to quality improvement initiatives, policies, and processes.

**Organizational Learning.** Accreditation was cited as promoting capacity-building, professional development, and organizational learning. The accreditation process itself could highlight practices that were working well, and may have a spill-over effect, whereby the accreditation of one service helps to improve the performance of others. Accreditation was also cited as enhancing the organization’s understanding of the continuum of care. **Healthcare industry benefits** were also cited by accreditation promoting sharing among healthcare organizations of policies, procedures, and best practices.

**Staff Effectiveness.** Accreditation was cited as contributing to the effectiveness of the organizations’ staff in the following ways: strengthening interdisciplinary team effectiveness; promoting an understanding of how each person’s job contributes to the healthcare organization’s mission and services; providing a team-building opportunity for staff and improved their understanding of their coworkers’ functions; and contributed to increased job satisfaction among physicians, nurses, and other providers.
Reduced Costs. Accreditation was cited as decreasing liability costs and mitigating the risk of adverse events, which would ultimately also reduce costs. Also cited was that accreditation could impact costs by helping identify for organizations areas needing additional funding and then providing a platform for negotiating this funding.

Research evidence supporting the benefits of accreditation versus the costs is also building. Longo et al in 2007 published a study that demonstrated that TJC accredited hospitals showed significant improvement over 18 months, while non-accredited hospitals did not, in patient safety system implementation. Menachemi et al in 2008 examined common surgical procedures in ambulatory surgery centers in Florida and compared outcomes for AAAHC or TJC accredited centers to non-accredited centers -- while TJC accredited center patients were less likely to be hospitalized after colonoscopy, no other differences were found. Lutfiyya et al in 2009 compared accredited and non-accredited rural critical access hospitals on 4 clinical core process measures and found accredited hospitals had better performance for 4 of 16 indicators. Schmaltz et al in 2011 evaluated changes in hospital performance between 2004 and 2008 for TJC accredited and non-accredited hospitals by leveraging CMS required and publically reported measures. These authors concluded that accredited hospitals tended to have better baseline performance, larger gains over time, and more likely to have high performance in 2008 on 13 of the 16 measures. Chassin et al (2010) provide data on TJC accredited hospitals’ greatly improved performance with 4 publically reported measures between 2002 and 2009, but also acknowledge that measurement could be costly. These authors proposed a conceptual framework with 4 criteria to guide the development of measures that are used for future public accountability (i.e. accreditation, public reporting, or pay-for-performance criteria).
Continuous Regulatory and Accreditation Readiness

Organizations that are not far along in the journey for high reliability may employ just-in-time regulatory or accreditation readiness models, which come with great financial and personnel costs. When organizations use just-in-time programs with ramp-up activities in the months prior to anticipated surveys, tremendous additional resources are required to demonstrate regulation or standard compliance. Extra staff or extra time is required for self-assessments or gap analyses, corrective actions to assure compliance, meetings for policy revision approvals, and front-line staff education on policy revisions, operational process improvements, and expected survey procedures. These organizations experience tremendous relief when surveys are completed and may commit to a vision that the next 2- or 3-year cycle would be different. However, organizational memory can be short and competing priorities replace the vision of sustained compliance. Organizations that experience unplanned surveys with numerous citations also experience a crisis-management cycle that requires tremendous unplanned additional resources. Compliance issues can be costly to organizations in terms of financial outlays for corrections, public reputation damages which lead to further financial losses in competitive markets, and staff turnover as the work environment is no longer satisfactory.

The goal of continuous readiness programs is to break crisis management cycles and just-in-time cultures to provide continuous safe quality patient care and sustained compliance with evidence-based practices, professional standards, and regulations. Key components of successful readiness programs include leadership commitment, manager accountability, requirement oversight, routine self-assessment, staff education, staff recognition, survey procedure plans, and post-survey oversight (Figure 1).

(Insert Figure 1)
1. Leadership Commitment

Leadership commitment to continuous readiness must be in place for programs to be successful and sustained. Leaders must be willing to change their organization’s culture to one of readiness, which requires the leaders to commit to personal change and create an environment where the values, ways of thinking, managerial styles, paradigms, and approaches to problem solving support a culture of readiness. Leaders must be patient and persistent to see this transformation through by defining what readiness looks like within their organization, aligning staff with that vision, and inspiring staff despite obstacles that will surface.

To commit, leaders must understand the business case for compliance and the costs of noncompliance. Costs may be known from previous ramp-up activities or noncompliance situations, or there may be potential costs from adverse media attention and loss of business. With the expanding of culture of transparency and public reporting of performance measures, organizations are subject to scrutiny from a variety of perspectives once media attention is drawn to them. The business case for continuous readiness also includes the impact on staff of ramp-up activities and crisis compliance management. Staff and managers can experience frustration and burnout with crisis compliance management and seek employment elsewhere, thus depleting organizations of experienced employees (those who possess crucial institutional memory).

Leaders must include continuous readiness within organizational strategic priorities in order to change the culture. It must be part of the operational budgeting process, part of key leadership activities, and a key topic that leaders inquire about in routine discussions with staff and managers. Leaders also must be willing to hold managers accountable for readiness responsibilities.

2. Manager Accountability
Managers play a key role in continuous readiness activities. Compliance is evaluated by what happens at the point of care delivery – which managers are accountable for. Policies and procedures provide the guidance and structure for those providing or supporting care delivery, but actual practice and policies must be aligned to achieve compliance. It is the managers role to determine when practice and policies are inconsistent, and to take action understand the root cause and corrections required for either policy adjustments or staff behavior adjustments.

Healthcare quality professionals in leadership roles cannot be the lone voices requiring compliance in complex organizations. The management team provides operational oversight within an organization and is the key to ensuring continuous compliance within their areas of accountability. Healthcare quality professionals must provide the program structure and education to help managers understand the requirements. New managers have steep learning curves to understand not only their departmental operations but also functional interrelatedness and regulatory and accreditation requirements. As managers learn to juggle operations, fiscal accountabilities, staffing, and public relations, they also must incorporate sustained compliance into their busy days. Unfortunately, it may be easier to allocate time to the faces and duties of the given day, rather than to proactive readiness responsibilities. Thus, the culture of the organization and the leaders’ strategic priorities will be determining factors in the success of readiness programs.

3. Requirement Oversight

A critical component of a continuous readiness program is a defined process to ensure that the organization is aware of changes in standards or regulations. Changes may be in the form of additions, deletions, or clarifications. Most regulatory or accreditation agencies have defined processes for changes; these usually involve notification to the affected organizations and a
period of time where comments or feedback on proposed changes are accepted prior to their publication. Clarifications may also be found in Frequently Asked Questions (FAQ) documents as well. Healthcare quality professionals should check with the agencies and organizations that survey their facilities to understand the relative frequency with which changes are made; the process for assimilating public feedback and comments from affected organizations; and the notification process to the affected organizations, including the medium (e-mail, paper letter, website announcements) and whom in the affected organization communications are directed (e.g., the chief executive officer versus the regulatory professional).

Once changes are identified, gap analyses must be completed to understand implications to the organization. Operational leaders and oversight committees will need guidance as to the scope and urgency of required changes. It is helpful to create a notification list of individuals within the organization who should receive communications related to standards. These communications are most effective when they are put into context for the recipient. For example, the communication should include a description of the change, the agency making the change, actions required on the part of the recipient, risk assessment of the change, and deadlines associated with required actions.

4. Routine Self-Assessment

Routine self-assessment is a cornerstone of continuous readiness programs. The ability to evaluate compliance of key regulatory and accreditation requirements is a critical step in this process. In the just-in-time preparation model, compliance is not sustained, but fluctuates in response to known survey cycles -- compliance improves immediately before a survey and gradually declines after each survey. The goal of continuous readiness programs is the opposite - sustained compliance. To do this, an organization must evaluate its compliance state
periodically. Two common self-assessment models are discussed below.

**Annual assessment.** With an annual self-assessment model, organizations plan for a thorough assessment once a year, often at the beginning of a fiscal year, with the results used to drive a compliance work plan. Resources are dedicated for the review, whether conducted internally or by an external consultant, as time is required for content experts to conduct actual reviews and document their findings. In this model, an assessment is completed and presented to leadership and quality oversight committees and often to an organization’s board of directors/trustees. Ideally, this report is in the format of a gap analysis related to specific standards, with findings and recommendations written in a manner that facilitates corrective action planning. Once the findings are presented, corrective action plans must be developed and monitored on an ongoing basis. Many organizations find that monthly or bimonthly status reports on corrective actions provide the oversight necessary to ensure course correction to achieve compliance. Using quarterly status reports runs the risk that the organization will not be aware of slippage. The advantage of an annual assessment is that the assessment is planned, resourced, and completed in a relatively short period of time allowing for action plan development, implementation, and monitoring throughout the remainder of the year. This model lends itself to assistance from resources such as internal corporate consultants or external consultants who facilitate the rapid completion of the assessment. A disadvantage of this model is that it requires dedicated resources to complete the assessment within a defined short period of time, as opposed to integration into other organizational activities or duties.

**Ongoing self-assessment.** With an ongoing assessment model, organizations plan for a thorough assessment over the year, often dividing the workload into smaller monthly activities. Resources may not be dedicated for the review, rather, responsibility may be an additional duty
assigned to existing staff (one or many), and time is taken from other accountabilities to complete tasks within the scheduled timeline. Documentation of findings for leadership action may be done centrally by one person or department or by each person completing an assessment segment using a reporting template. In this model, as the assessment components are completed, they should be presented to leadership and oversight committees. Presentation to the organization’s board of directors/trustees can be periodic as a summary of the assessment components rather than a single completed report. This report is also most useful when in the format of a gap analysis related to specific standards, with findings and recommendations written in a manner that facilitates rapid corrective action planning. Once the findings are presented, corrective action plans must be developed and monitored on an ongoing basis. Monitoring schedules in this model however are more complex as they must incorporate scheduled assessments to be completed as well as follow-up activities on those that have been completed. Many organizations find that at least monthly status reports are required on assessment components and the corrective actions in order to provide the oversight necessary to achieve compliance. Quarterly status reports are not recommended because there is a high risk that the organization will not be aware of slippage soon enough to take appropriate action. The advantage of an ongoing assessment is that the assessment can be resourced and integrated into operational activities and reported over an ongoing (but defined) period of time, allowing for action plan development, implementation, and monitoring throughout the year. A disadvantage of this model is that it requires focused project management to ensure completion of the entire assessment and to ensure monitoring and oversight of required corrective actions. There is a risk of not completing the entire assessment and it also may be difficult for the organization to have a “snapshot” of compliance to understand performance.
Regulatory or accrediting agencies may have tools available to help organizations manage self-assessment activities. Access to information such as easy-to-use checklists may be readily available on Internet sites. Additional paper-based or computer-based project management programs designed specifically for the identified regulations, accreditation, or certifications programs also may be purchased directly from the agencies or from third-party entrepreneurs. External consulting organizations also will provide educational programs or tools for evaluation or preparation activities on a fee-for-service basis.

5. Staff Education

Continuous readiness programs require solid organization-wide education programs with staff participation from all levels within an organization. Healthcare quality professionals must develop an effective and efficient education plan that targets defined levels within the organization:

- Leadership must receive information to prioritize resources for readiness, to role model required changes in behavior, and to speak to key leadership standards when surveyors visit their facilities.

- Managers must have information related to care delivery requirements, structure or process requirements, as well as required documentation that must be available to surveyors. They are accountable for their staff’s compliance so managers also will need to participate in staff education programs, often becoming the staff educator after train-the-trainer programs.

- Front-line staff must receive information to comply with standards and regulations related to direct care delivery, which will be found in policies and procedures related to their work. There will also be documentation requirements that they must understand and comply with such as specific care documentation, equipment checks for maintenance or
performance within defined parameters (i.e. test result or temperature ranges),
communication documentation with transitions in care, or required education and training
that must be documented.

Effective education plans must target defined departments within an organization. For example, key messages for large care delivery departments such as nursing may be different than key messages for smaller ancillary departments, or key messages for specialty department departments may be different. If programs are not designed specifically for an intended audience, participants may believe that the majority of the material applies to another department or may be unable to apply the message to their own department. Organizations may have education departments that can help design these programs and provide the structure for delivery.

Just-in-time training has been a tool used historically in readiness programs. This education is timed to be provided not too far in advance of an anticipated survey, so as not to run the risk of staff or leaders forgetting the information prior to survey, and not too close to the survey when staff and leaders become overwhelmed with information. Pocket guides or booklets have been popular vehicles for this type of education, as well as quick reference attachments to name badges. Although there is always a place for just-in-time education, it cannot be the foundation of an effective readiness program when most surveys are unannounced. The focus of just-in-time training should be on what staff and leaders can expect to take place during an actual survey, rather than the regulations and requirements that will be surveyed. For example, just-in-time education may be effective to inform staff what the survey agenda will look like, types and numbers of surveyors or inspectors to expect, planned interview sessions (who will participate and anticipated topics), and documents that might be required during the survey process.

Successful continuous readiness education programs are the outcome of creative
education modalities that reach staff and leaders alike, and effectively impart key messages and reinforcing them across the organization. Classroom training sessions can be used however this delivery method requires conference room space for large numbers of participants, as well as flexible program scheduling (times and number of programs) to allow participants with various shift and work schedules to participate. Newsletters have been used successfully to reach staff on two or three different shifts and with 7-day operations -- paper newsletters suit the culture of some organizations, while others find them onerous to create and publish regularly, and the printing costs to be prohibitive therefore electing to use electronic newsletters. Storyboards or poster boards placed in key locations throughout the facility can efficiently educate staff and patients or clients alike, and can be created inexpensively using desktop publishing programs. Large organizations may have teleconferencing capability to broadcast educational programs throughout an organization’s multiple campuses; these also can be recorded for ongoing training purposes. Teleconferencing technology has improved to allow moderators to manage multiple telephone lines and still produce effective audio conferences with large numbers of participants. Many organizations have available Internet services for meetings or training programs that can be viewed directly from a computer station and heard through the computer or associated telephone lines. Internet or computer-based learning programs have become increasingly effective tools as the technologies continue to advance.

Healthcare quality professionals must be creative in developing effective ongoing programs as the workforce is constantly changing as heath care staff change roles or organizations. One tool for development of flexible program scheduling has been the use of train-the-trainer educational sessions. This option allows a program to be developed and taught to those who will in turn teach the program to others. For example, healthcare quality
professionals might sponsor a program for all managers, who in turn will be responsible for teaching the program to their individual staff. This is an effective method to reach large numbers of staff on varying shifts and schedules, but it depends on the commitment of each manager to follow through. Self-study modules, whether paper-based, computer-based, or video-based, also are efficient means to deliver standardized, ongoing education.

Creating fun educational programs is an essential part of successful continuous readiness programs. Staffs appreciate an opportunity to make learning fun and developing simple incentives through competitions can help to generate enthusiasm for the program. Television game shows serve as program models with “survival” tactics or a question-answer format, as well as computer or board game formats, and crossword puzzles for newsletters. This is an opportunity for quality professionals to exercise their creativity in a field that can be perceived as boring!

Education calendars should be planned in advance as a cohesive program. Creating an ongoing series will be more effective than a sporadic offering of seemingly unrelated topics. Education programs may best be long-range programs designed around multi-year survey cycles. The following is an example of an education program organized around a survey cycle. Note, that if the survey is anticipated to be within a defined window of time, the “year” may not be a calendar year for the educational program – the year could be August to July for example.

**First year (pre-survey year).** The first year focus is to keep staff and leadership apprised of key standards and regulations (and anticipated changes) and the associated agencies that survey the organization. Self-assessment compliance gap analyses would serve as the foundation of compliance activity and the education required as the organization adjusts policies and procedures. Programs planned throughout the year could also highlight functions
or clusters of topics for defined audiences. For example, a series might be planned for managers and leaders, highlighting accountabilities that cross department boundaries. A series of programs to build skills related to regulatory, accreditation, or quality improvement should also be considered. Examples of skill-building programs might be topics related to basic business knowledge to highlight competitive realities that drive the need for high-quality, safe patient care; quality improvement models; improvement team facilitation; committee management (facilitation, chairmanship, committee support and organization, minutes); overview of regulatory and accrediting organizations or agencies; and change management (including programs that teach employees to lead within their spheres of activities).

**Second year (survey year).** The focus of this year could be to prepare staff and leadership for anticipated survey activities. A survey can be very intimidating for staff and managers alike, and having knowledge of what to expect can help everyone be successful. Kick-off educational programs might incorporate basic information around the planned survey to educate staff about the purpose of the survey, the value of the survey to the organization, expected windows for unannounced surveys (dates), and expectations of staff, managers, and physicians during the survey process.

To prepare the organization for positive interactions with survey teams, survey etiquette should be included as an education topic, including appropriate behavior during the survey and suggestions on how to interact with surveyors.

- Conduct orientation sessions for nursing unit charge nurses or departmental managers, physicians, and residents to help them understand their role and what to expect during the survey.
• Orient staff who likely will be in roles as surveyor escorts and scribes. Familiarize them with their role; provide tours of the facility to ensure that all escorts know the campus thoroughly and are aware of proper routes for guests; coach them to “tell the story” of things the organization is proud of (which might be triggered by things noted during the tour); and orient them to communication strategies with the organization’s command center.

• When an orientation session will be provided for the surveyor team, conduct practice sessions with live audiences to enable the speakers to become familiar with the equipment, material, and questions that might come from the surveyors. Ensure that all managers and leaders attend the practice sessions so that they are aware of the orientation content and key areas what will be highlighted.

• Practice known interviews or patient tracer activities with involved staff and include back-up personnel who may be called in at the last moment.

• Practice interviews with staff, focusing on questions such as “show me how….” or “show me where…”

Mid-year programs might emphasize “hot topics” or key standards or regulations that will be a focus during the survey. Education may highlight how the organization complies with these important topics and information about targeted performance improvement initiatives related to these key topics. There also should be a focus on programs that the organization is proud of and success stories from the field -- all staff should be aware of the organization’s good work and be able to express their pride in the organization during the survey.

End-of-the-year programs might focus more on just-in-time topics with practice
sessions for known interviews or survey sessions to help leaders, managers, and staff feel comfortable while participating in the actual survey. Follow-up programs might focus on the survey results, opportunities identified for improvement, and anticipated action plans associated with these findings.

**Third year (post-survey year).** The focus of this year is sustained compliance, especially in areas where the survey identified opportunities for improvement. The facility’s self-assessment gap analysis and follow up on corrective action plans should drive the educational program, as well as awareness of changing regulations and standards. This is also a good year for development of new programs or initiatives to improve patient care.

6. **Staff Recognition**

Staff recognition and rewards for participation in continuous readiness programs is a critical component for successful programs. Staff are experiencing ever-increasing lists of tasks they must accomplish and documentation they must complete, while trying to meet organizational expectations for efficiency and customer service. Participation in proactive readiness or crisis-prevention regulatory activities may not be a priority unless leadership establishes a culture of readiness as an organizational priority. Recognition can be very simple and still be effective. Leadership acknowledgment through personal words of thanks, notes of appreciation, or public acknowledgment in committees or meetings are all effective means of recognition. Regulatory professionals need to help leaders be successful by providing leaders with information that can be used for recognition – the stories or examples of staff and managers that have exceeded expectations are important to pass on. Timely recognition, even if simple, is more effective than waiting for formal recognition forums that are few and far between and may
not be well attended. Participation in readiness activities can be rewarded with small treats such as candy, trinkets such as pens or pins, or coupons for coffee, lunch, or the farmers market are appreciated by staff on all shifts and are most effective when given at the time of participation. Leadership rounds on the clinical units are also an effective way to acknowledge staff members and to solicit their input and feedback on further opportunities to support and improve the continuous readiness programs.

7. Survey Procedure Plans

Planning survey procedures should be planned in advance based on what is expected with anticipated surveys. Typically, when surveyors arrive at a facility, they report to administrative offices and announce their visit. They may or may not present formal letters describing the reason for the visit. Administrative support staff should find a comfortable location for the surveyor to wait while the appropriate administrator is located. After a senior member of the leadership team welcomes the surveyor, he or she must request to see a photo identification card from the represented agency or organization and obtain a business card from the surveyor (to ensure that contact information is available for any required follow-up). The survey should not proceed without proper surveyor identification. As the surveyor describes the purpose of the visit, the organization can use this information to assemble the appropriate team of individuals who have accountabilities related to the purpose of the visit. The surveyor may ask to visit departments or tour the facility, and they should be accompanied if at all possible. They may request to see copies of documents, review medical record documentation, review HR or credentialing files, observe the provision of care, and interview staff as well as patients/clients/residents and their families. Organizations should establish policies to guide staff as to what documents may be copied upon surveyor request and what documents need to be
Healthcare quality and regulatory professionals have the responsibility to develop and manage survey procedures for the organization as they serve as internal consultants for the organization. The coordination required to achieve favorable accreditation or certification status or successful regulatory licensing or certifications must be delegated to those individuals with the most knowledge about healthcare quality, regulations, and standards interpretation and implementation. This coordination role can be delegated to a leader or manager within the quality area, or to a designated role in larger organizations such as a Regulatory Director. Important preparation tasks for organizations to complete are generally outlined in survey manuals and can be planned in advance for each anticipated survey. Formal plans are recommended, with multiple staff and leaders familiar with the process. The organization’s plan will likely include the components described in the following section (Figure 2).

(Insert Figure 2)

**Survey Applications.** Although each agency has a unique process for accomplishing its survey, they will all have an application process for a new licensing survey or an initial accreditation or certification survey, or for extending licensing or accreditation for expanded services or new buildings. These applications will likely require updates for continuing or renewing licensing or accreditation. Application information is often readily available in publications or on Internet sites that help guide facilities through an often-tedious process. Reviewing application requirements far in advance may be helpful to fully understand the data needed to complete the application and determine the internal source for the organization’s information. Survey fees may be required during the application process or they may be billed to the organization after the survey is completed. Many applications can be completed...
electronically through the Internet on secure websites and some agencies now require electronic application processes. Inquire with the agency in advance as to the options that are available for application submission, deadlines for submission, anticipated fees, and required signatures.

After the application has been submitted, the review agencies initiate their survey planning process. They may provide the organization with an anticipated “survey window” – a time frame for when to expect an unannounced survey. The survey windows vary widely, but clues can help the organization know what to expect. For example, it may be known to be within four to six months after the application, or based on the agency’s scheduling availability or backlog, or known to be on a cycle of approximately 24 to 36 months.

The actual survey may begin prior to on-site survey activities through desktop review — the submission of materials electronically or the mailing of documents for review by the survey team in advance of arrival. Understanding submission requirements is critical to a successful survey; it ensures that documents focus on the surveying agency’s specific criteria and information is not lost in too much submitted information. Existing documents may lack the focus required for submission within defined page limits or within form boundaries and require reformatting for this purpose. In addition, performance data, complaint data, news articles, financial statements, and other publicly available data may be gathered by the agency to help prioritize vulnerabilities during the on-site survey process. Expect requests for additional information or clarifying information prior to the on-site survey. Also, expect to receive planning information after submission of the application, with at least generic schedules of survey activities to guide preparation and planning for the actual survey event.

**Survey Readiness Oversight.** The best way to provide preparation oversight is through the formation of multidisciplinary and interdepartmental workgroups or ongoing committees
representing the full scope of services included in the anticipated survey(s), whose composition will vary depending on type of organization and services provided (e.g., hospital, managed care organization, long-term-care facility, home healthcare agency, ambulatory care center, etc.). At a minimum, the workgroup should consist of the healthcare quality professional and representatives from administration, nursing, key ancillary departments, medical staff, and the possibly the governing board. In the hospital setting, other members might include the safety officer, risk manager, and director of health information management/medical records. In a managed care organization, additional members might include customer relations, physician relations/medical staff coordinator, information systems/data processing, and the benefits administrator. The medical staff have a large role and accountability for compliance and for performance improvement, however it may be challenging to schedule time for their participation in planning activities and to clear their schedules when the actual survey process commences. Medical staff participation requires constant communication as information becomes available. The frequency with which survey readiness groups meet will vary depending on the outcome of ongoing self-assessments and available resources to complete identified tasks. If the oversight and planning groups perform this work in a continuous fashion and the organization has created a culture of readiness, the last-minute rush and accompanying stress will be lessened as the survey window approaches. A number of publications are available with suggested checklists to assist with survey preparation, as well as commercial educational programs. The most important element, however, is a coordinated, ongoing effort to meet the intent of the regulations or standards. Table 8 provides examples of activities to prepare for anticipated surveys.

*(Insert Table 8)*
**Space Planning and Hosting.** Most organizations are challenged with providing adequate conference room space during unannounced surveys with unknown survey team sizes. Space planning is a critical role to keep the survey team comfortable and to keep confidential information and conversations out of public areas. There can be considerable disruption and chaos caused when standing room reservations need to be postponed, cancelled, or relocated during the survey. Many organizations plan in advance which conference rooms are predominately used and can be cleared on a moments notice with minimal impact to care. For anticipated survey activities such as accreditation, the organization may be aware of anticipated interviews and can prepare attendee lists for each activity to pre-determine anticipated conference room size and set-up requirements. For relocated or cancelled meetings, a communication system will need to be established during the survey to notify participants of new room locations for meetings moved and to assure that the survey meetings are not interrupted. All reserved survey rooms should be checked for set-up and working equipment daily during the survey.

**Surveyors’ workroom.** A conference room or office space for surveyors to work in privacy will be required. This should be in a quiet location without noisy meetings in adjacent space. The room should be secure at night and when surveyors are out on clinical units. Set-up will require a workspace with room for a computer, power outlet, and chair for each surveyor, as well as a food service table, document table, and available telephone. Surveyors may also require Internet access to relay information to their agency’s home office. Anticipate that this room will be used all day during every survey day and will not be available for other use.

**Command center (or war-room).** Determine a conference room in a convenient location relative to the surveyor workroom where your organization can manage the survey process. This
room requires multiple workspaces to accommodate computers, electrical and computer lines, and chairs for staff, in addition to food service and document storage. Arrange for the room to have at least two telephones and a facsimile machine, and at least two computers to allow rapid access to clinical systems and policies or procedures concurrently. Printers should be identified that are brought to the room or are near by. This room will be used all day during every day of the survey and should not be available for use in the evenings by others to eliminate the need to move and reorganize confidential material daily. The room should be locked at night.

**Other conference rooms.** If the survey schedule includes interviews, a daily briefing with surveyors or daily special issues resolution time, consider where to hold these sessions. Select a location that will comfortably hold anticipated participants away from surveyor workrooms or command center operations so that survey work is not interrupted. Consider also if the facility wishes to “huddle” with key staff, surveyor escorts or scribes, and leadership during lunch hours and at the beginning or end of the day that is away form the command center. The facility may also wish to set a room aside for leadership strategy sessions during the survey process. At the end of the survey there is usually an exit conference, which will require chairs for staff and table and chairs for surveyors at the front of the room. Based on the number of anticipated participants, this could require a large conference room, in which case the need for microphones should be considered.

**Hosting considerations.** Additional hosting considerations relate to keeping staff and surveyors comfortable during the survey. Clarify with the lead surveyor if the team is able to accept food from the organization (many governmental employees can not) and to determine if there are any food allergies or preferences to be aware of. Consider ordering food daily for a light breakfast and lunch with delivery to the surveyors’ workroom and the organizations
command center. Determine if the facility wishes to provide lunch for the management team, scribes and escorts involved in the survey as they may not have time to go and get food and be back for their survey duties in a timely manner. Make sure bottled water, coffee, tea, and snacks are available throughout the survey. Remember to have rooms stocked daily with paper napkins, plates, utensils, and cups and arrange with housekeeping for frequent trash removal after meals so that trash is not overflowing and food odor is not apparent. Identify key restrooms in advance that may have atypical heavy use during the survey to ensure they are clean, in good repair, and stocked, which may require supplemental service schedules.

Survey Command Centers. Communication is the key to a successful survey process. It is helpful to have a central point of contact for surveyors and for the facility to manage and track all requests for information or interviews – this is often referred to in military terms as a “war room” or “command center.” The command center should have one person identified as being in charge -- often this is the organization’s survey coordinator. The command center should be organized in advance with defined staff roles and should track key information including each surveyors location, key activities, and issues they identify, patients reviewed or interviewed, paper or closed charts requested, employees interviewed or files reviewed, physicians interviewed and involved in patient care, and all surveyor requests. Procedures to consider in planning for smooth survey operations are listed below.

- Command center locations are often large conference rooms or executive suites. Determine what office supplies are required in the course of a survey such as chart pads, easels, grease boards, clipboards, extra telephones, facsimiles or computers, projectors if electronic tracking programs are used, etc. Many organizations keep the require supplies assembled in boxes or cabinets that are ready to be transported to the command center when unannounced surveys
begin.

- Determine the communication equipment required specifically for this function. Many organizations have a room where this equipment is located permanently so that the room is ready for announced or unannounced survey operations, as well as for natural disasters. Develop the process to test equipment when a survey starts. Dedicated phone and facsimile lines will be helpful and more than one phone line will likely be required to allow open lines for return pages or call backs, and to allow more than one person to use the phone at a given time. One phone line should roll over to another line to eliminate busy signals. Determine the number of computers needed and ensure that wireless access or active lines are available for mainframe computer access.

- Determine a tracking system for surveyor requests to assure all requested information is provided to the correct surveyor. Tracking should include the responsible parties to provide the information and status of the requests through to closure. Consider a file or box for staging individual surveyor’s requests while gathering the complete packet of requested information. Many organizations keep a copy in the command center of all documents provided to surveyors during the course of the survey to assist the organization with problem solving compliance issues.

- If scribes or escorts are accompanying surveyors, they should be provided with an efficient means to communicate directly with the command center for any concerns identified or surveyor requests such as dedicated phone or facsimile numbers. Determine the tracking system for this type of information (i.e. paper based notes, chart pads, electronic logs), as it will be a rich resource of information for risk mitigation activity during the survey.

- Develop contact lists of key staff, managers, or departments. The command center will
need phone numbers that are always answered for key departments (that don’t go into
voice mail), and cell phone or other portable phone numbers or pagers that are carried by
key leaders or department contacts. These same departments or leaders will also need to
know the number to reach the command center during the course of the survey, or the
link to any online or intranet-based communication tools used by the organization.

- Based on the type of organization being surveyed, there will be key documents that are
either required or often requested. Assemble these documents in binders or electronic
folders in a known location to assure easy access when unannounced surveys take place.

An infrastructure will be required to keep these documents current. An example of
documents to consider for a hospital includes current organizational charts, program
descriptions, plans for the provision of care, governing body structures, professional staff
bylaws, copies of licenses, governing body minutes and key quality and administrative.

8. Post Survey Procedures

Survey Exits. At the close of most surveys, the surveyor(s) conduct a formal exit
conference prior to leaving the facility. This provides an opportunity for the organization to
understand the surveyor findings and to clarify findings if there are questions. Leadership should
request the surveyors to summarize the findings and deficiencies that will be cited, and to
disclose anticipated next steps in the survey process. If the surveyor does not leave a final report
at the time of the survey (most governmental agencies do not), inquire as to the expected
timeline for receipt of this important document.

After the survey is completed and the surveyors exit, it is important for the organization
to conduct their own debriefing as soon as possible to evaluate the survey process. Notes from
the command center should be reviewed and compared to surveyor comments made during the
exit conference where deficiencies were described. An evaluation of how the organization managed the survey process should be completed also evaluate the preparedness of management and staff in responding to questions; adequacy of documentation provided; and the flow of the survey process. Adjust the preparation plans for future surveys based on this evaluation.

Senior leaders such as the CEO, chief of staff/medical director, or chairman of the board should consider a special communication to the organization’s staff to share the survey outcome and extend appreciation for their collaborative efforts. Organizations may also wish to provide post-survey celebrations when large surveys are successfully completed to recognize the contribution of the staff in this formal milestone.

**Corrective Action Plans.** When deficiencies are cited or even suspected from a survey, the organization should design and implement corrective actions immediately -- even while waiting for the final report. Final reports can be delayed when they require a State agency to submit a report to a Federal agency for final approval of the survey decisions, or if accreditation agencies wish review of challenging findings by their central office. When the report is delayed, it will be difficult to remember the details of the survey citation or leadership attention may be on new matters, making corrective action planning more difficult. Even with delayed reports, a short deadline may be mandated (10 days, for example) to submit corrective actions. Survey findings should form the basis for future leadership oversight on appropriate committee and leadership meeting agendas.

The name used for the citation document required to respond to deficiencies varies widely from planning documents that describe how the organization will fix deficiencies (corrective action plan, plan of corrections, or improvement plan) to documentation of how and when the deficiencies were corrected (evidence of standards compliance). These documents are
written in response to a survey or inspection, but also can be used for internal assessments or in response to internal gap analyses to address upcoming changes in standards or regulations. These documents are written by a central person or department (often the quality and performance improvement department), but require input from many different departments or staff for both their development and the design of actions, and for oversight of the actions taken.

The most common format for these documents is a table that can assist project management by allowing different document sorts depending on the purpose of the review. The table structure should have columns for the topic or standard cited, compliance issue for correction, planned actions, deadline for completion, and the name of the person accountable for the action. In complex organizations or difficult surveys with many findings, it may be useful to also include a column for the oversight body or committee and their schedule for status reports. Rows in the table or grid address individual improvement topics.

Development of adequate and feasible action plans is only the beginning of an effective continuous readiness program. The most difficult part of the program is oversight to ensure full implementation, evaluation, and revisions as necessary until full compliance sustained. Healthcare quality professionals facilitate tracking mechanisms for explicit communication related to accountability expectations, timelines for completion, and oversight reporting, plus responsibility for escalation when further actions are required. Leadership cannot facilitate the removal of obstacles and barriers of which they are not aware, and leadership’s prioritization, sustained support, and established culture of readiness will be important survey success factors.

Summary

This module began with a review of Federal and State regulators that are required by law to have oversight of the provision of healthcare. The regulations and regulatory agencies that
will be important to healthcare quality professionals vary widely depending on the segment of the healthcare continuum where quality professionals are employed. State laws vary widely as do State agency resources for licensing and enforcement – a situation that creates variability in the knowledge required by regulatory professionals in the healthcare industry. Just as regulations vary across the healthcare continuum, accreditation and certification requirements vary. Each segment of the industry is driven by a variety of market pressures and imperatives that will influence leadership decisions related to accreditation or certification programs. And leadership commitment to high reliability with sustained continuous compliance will be transparent with the commitment of resources for robust readiness programs.

The intention of this module was to provide an overview for healthcare quality professionals to gain insight into regulation, accreditation, and certification requirements and agencies. Armed with insight, regulatory professions will want to design their own course of study to gain the knowledge needed to keep their patients, staff, and organizations compliant. Sustained compliance allows staff’s attention to focus on the provision of safe, high-quality patient care in their unique segment of the healthcare continuum and in their individual regulatory environment. Questions to explore within one’s own institutions should focus on who regulates individual organizations from the federal, state, and local perspective; and to determine the business strategy for accreditation and certification of programs and services to understand where to investigate specific requirements and survey procedures. Regulatory and accreditation requirement oversight is a critical business imperative for organizations committed to high reliability and sustained compliance, and an important component of quality professional’s unique knowledgebase.
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Accrediting Association for Ambulatory Healthcare. www.aaahc.org

Agency for Healthcare Research and Quality. www.ahrq.gov

American College of Radiology. www.acr.org/accreditation

Centers for Disease Control and Prevention. www.cdc.gov

Centers for Medicare and Medicaid. www.cms.hhs.gov

Clinical Laboratory Improvement Amendments. www.cms.hhs.gov/clia

College of American Pathologists. www.cap.org


Commission of Office Laboratory Accreditation. www.cola.org

Commission on Accreditation of Rehabilitation Facilities, International. www.carg.org

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Det Norske Veritas. www.dnvusa.com/industry/healthcare

Emergency Treatment and Active Labor Act. www.cms.gov/EMTALA

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Food and Drug Administration. www.fda.gov

Healthcare Facilities Accreditation Program. www.osteopathic.org

Health Insurance Portability and Accountability Act. www.hhs.gov/ocr/privacy

National Quality Forum. www.qualityforum.org

Occupational Safety and Health Administration. www.osha.gov


Quality Care Finder. www.cms.gov/center/quality.asp

National Committee for Quality Assurance. www.ncqa.org

The Joint Commission. www.jointcommission.org

URAC. www.urac.org
**Other Resources**


Title 42--Public Health, Chapter IV--CMS, DHHS, Subchapter G—*Standards and certification, Part 488 – Survey, certification, and enforcement procedures.* Retrieved from http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=538d90a4e5b9e05e13ccee8902ccfa35&tpl=/ecfrbrowse/Title42/42cfr488_main_02.tpl

Use of State Agencies to determine compliance by providers of services with Conditions of Participation[^609]. Retrieved from http://www.ssa.gov/OP_Home/ssact/title18/1864.htm

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* Eligible to receive only those reports authorized by Section 1921.  
** Eligible to receive only those reports authorized by HCQIA.

www.npdb-hipdb.hrsa.gov/resources/brochures/NPDBAndHIPDBComparisonChart.pdf

April 2011  
NPDB-02449.02.02
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<tr>
<td>§482.23 Condition of participation: Nursing services.</td>
</tr>
<tr>
<td>§482.24 Condition of participation: Medical record services.</td>
</tr>
<tr>
<td>§482.25 Condition of participation: Pharmaceutical services.</td>
</tr>
<tr>
<td>§482.26 Condition of participation: Radiologic services.</td>
</tr>
<tr>
<td>§482.27 Condition of participation: Laboratory services.</td>
</tr>
<tr>
<td>§482.28 Condition of participation: Food and dietetic services.</td>
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<tr>
<td>§482.30 Condition of participation: Utilization review.</td>
</tr>
<tr>
<td>§482.41 Condition of participation: Physical environment.</td>
</tr>
<tr>
<td>§482.42 Condition of participation: Infection control.</td>
</tr>
<tr>
<td>§482.43 Condition of participation: Discharge planning.</td>
</tr>
<tr>
<td>§482.45 Condition of participation: Organ, tissue, and eye procurement.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subpart D Optional Hospital Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>§482.51 Condition of participation: Surgical services.</td>
</tr>
<tr>
<td>§482.52 Condition of participation: Anesthesia services.</td>
</tr>
<tr>
<td>§482.53 Condition of participation: Nuclear medicine services.</td>
</tr>
<tr>
<td>§482.54 Condition of participation: Outpatient services.</td>
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<tr>
<td>§482.55 Condition of participation: Emergency services.</td>
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<tr>
<td>§482.56 Condition of participation: Rehabilitation services.</td>
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<tr>
<td>§482.57 Condition of participation: Respiratory care services.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Subpart E Requirements for Specialty Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>§482.60 Special provisions applying to psychiatric hospitals.</td>
</tr>
<tr>
<td>§482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.</td>
</tr>
<tr>
<td>§482.62 Condition of participation: Special staff requirements for psychiatric hospitals.</td>
</tr>
<tr>
<td>§482.66 Special requirements for hospital providers of long-term care services (“swing-beds”).</td>
</tr>
</tbody>
</table>
Table 4
New York State Department of Health Administrative Code Excerpt

<table>
<thead>
<tr>
<th>New York - Administrative Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title 10. Department of Health</td>
</tr>
<tr>
<td>Chapter V. Medical Facilities</td>
</tr>
</tbody>
</table>

10 NYCRR 405.6 Quality Assurance Program
The governing body shall establish and maintain a coordinated quality assurance program which integrates the review activities of all hospital services to enhance the quality of patient care and identify and prevent medical, dental and podiatric malpractice.

(a) The governing body shall establish a quality assurance committee, at least one member to be a member of the governing body of the hospital and who is not otherwise affiliated with the hospital in an employment or contractual capacity. The quality assurance committee shall report its activities, findings and recommendations to the governing body as often as necessary, but no less often than four times a year. The quality assurance committee shall:

1. develop a written plan which details:
   - the establishment and implementation of a medical, dental and podiatric malpractice prevention program;
   - the manner in which the committee will relate to the medical staff executive committee, if any, the hospital governing body and the chief executive officer;
   - the manner in which the medical, dental and podiatric malpractice program will relate to other hospital administrative mechanisms and procedures;
   - the role and responsibility of each service or department in the quality assurance process; and
   - the authority of the committee regarding recommendation or implementation of corrective action;

2. administer the hospital quality assurance program to assure:
   - the identification of actual or potential problems concerning patient care and clinical performance;
   - the assessment of the cause and scope of problems identified;
   - the development and recommendation of proposed courses of action to address problems identified;
   - the use, in the revision of hospital policies and procedures, of information gathered regarding problems identified;
   - the implementation, through established mechanisms, of actions necessary to correct the identified problems;
   - the monitoring and evaluation of actions taken and the implementation of remedial action to ensure effectiveness; and
   - the documentation of all measures taken pursuant to this section in the quality assurance program.

(b) The activities of the quality assurance committee shall involve all patient care services and shall include, as a minimum:

1. review of the care provided by the medical and nursing staff and by other health care practitioners employed by or associated with the hospital;
2. review of mortalities;
3. review of morbidity in circumstances other than those related to the natural course of disease or illness;
4. review of infections, complications, errors in diagnosis, transfusions and results of treatments;
5. review of medical records, medical care evaluation studies, complaints, incidents and staff suggestions regarding patient care and safety, utilization review findings, profile analysis and other pertinent data sources;
6. the maintenance and continuous collection of information concerning the hospital's experience with negative health care outcomes and incidents injurious to patients, patient grievances, professional liability premiums, settlements, awards, costs incurred by the hospital for patient injury prevention and safety improvement activities; and
7. the committee shall oversee and coordinate the following:.............................
HFS 124.10 Quality Assurance

(1) Responsibility of the governing body
The governing body shall ensure that the hospital has a written quality assurance program for monitoring and evaluating the quality of patient care and the ancillary services in the hospital on an ongoing basis. The program shall promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(2) Responsibilities of the chief executive officer and the chief of the medical staff
As part of the quality assurance program, the chief executive officer and chief of the medical staff shall ensure that:
   (a) The hospital's quality assurance program is implemented and effective for all patient care related services;
   (b) The findings of the program are incorporated into a well defined method of assessing staff performance in relation to patient care; and
   (c) The findings, actions and results of the hospital's quality assurance program are reported to the governing body as necessary.

(3) Evaluation of care to be problem-focused: Monitoring and evaluation of the quality of care given patients shall focus on identifying patient care problems and opportunities for improving patient care.

(4) Evaluation of care to use variety of resources: The quality of care given patients shall be evaluated using a variety of data sources, including medical records, hospital information systems, peer review organization data and, when available, third party payer information.

(5) Activities: For each of the monitoring and evaluation activities, a hospital shall document how it has used data to initiate changes that improve quality of care and promote more efficient use of facilities and services. Quality assurance activities shall:
   (a) Emphasize identification and analysis of patterns of patient care and suggest possible changes for maintaining consistently high quality patient care and effective and efficient use of services;
   (b) Identify and analyze factors related to the patient care rendered in the facility and, where indicated, make recommendations to the governing body, chief executive officer and chief of the medical staff for changes that are beneficial to patients, staff, the facility and the community; and
   (c) Document the monitoring and evaluation activities performed and indicate how the results of these activities have been used to institute changes to improve the quality and appropriateness of the care provided.

(6) Evaluation of the program: The chief executive officer shall ensure that the effectiveness of the quality assurance program is evaluated by clinical and administrative staffs at least once a year and that the results are communicated to the governing body.
### Table 6
California State Department of Health Administrative Code Excerpt

<table>
<thead>
<tr>
<th>California - Administrative Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title 22. Social Security</td>
</tr>
<tr>
<td>Division 5. Licensing and Certification of Health Facilities, Home Health Agencies, Clinic, and Referral Agencies</td>
</tr>
<tr>
<td>Chapter 1. General Acute Care Hospitals</td>
</tr>
<tr>
<td>Article 7. Administration</td>
</tr>
</tbody>
</table>

T. 22 §70703 Organized Medical Staff
(a) Each hospital shall have an organized medical staff responsible to the governing body for the adequacy and quality of the care rendered to patients.
   (1) The medical staff shall be composed of physicians and, where dental or podiatric services are provided, dentists or podiatrists.
(b) The medical staff, by vote of the members and with the approval of the governing body, shall adopt written by-laws which provide formal procedures for the evaluation of staff applications and credentials, appointments, reappointments, assignment of clinical privileges, appeals mechanisms and such other subjects or conditions which the medical staff and governing body deem appropriate. The medical staff shall abide by and establish a means of enforcement of its by-laws. Medical staff by-laws, rules and regulations shall not deny or restrict within the scope of their licensure, the voting right of staff members or assign staff members to any special class or category of staff membership, based upon whether such staff members hold an M.D., D.O., D.P.M., or D.D.S. degree or clinical psychology license.
(c) The medical staff shall meet regularly. Minutes of each meeting shall be retained and filed at the hospital.
(d) The medical staff by-laws, rules, and regulations shall include, but shall not be limited to, provision for the performance of the following functions: executive review, credentialing, medical records, tissue review, utilization review, infection control, pharmacy and therapeutics, and assisting the medical staff members impaired by chemical dependency and/or mental illness to obtain necessary rehabilitation services. These functions may be performed by individual committees, or when appropriate, all functions or more than one function may be performed by a single committee. Reports of activities and recommendations relating to these functions shall be made to the executive committee and the governing body as frequently as necessary and at least quarterly.
Table 7
California State Health and Safety Code Excerpt

<table>
<thead>
<tr>
<th>California - Statutes</th>
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<tbody>
<tr>
<td>Health and Safety Code</td>
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<tr>
<td>Division 2. Licensing Provisions</td>
</tr>
<tr>
<td>Chapter 2. Health Facilities</td>
</tr>
<tr>
<td>Article 3. Regulations</td>
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</tbody>
</table>

H & S §1279.6 Patient Safety Plans
(a) A health facility, as defined in subdivision (a), (b), (c), or (f) of Section 1250, shall develop, implement, and comply with a patient safety plan for the purpose of improving the health and safety of patients and reducing preventable patient safety events. The patient safety plan shall be developed by the facility, in consultation with the facility's various health care professionals.
(b) The patient safety plan required pursuant to subdivision (a) shall, at a minimum, provide for the establishment of all of the following:
   (1) A patient safety committee or equivalent committee in composition and function. The committee shall be composed of the facility's various health care professionals, including, but not limited to, physicians, nurses, pharmacists, and administrators. The committee shall do all of the following:
      (A) Review and approve the patient safety plan.
      (B) Receive and review reports of patient safety events as defined in subdivision (c).
      (C) Monitor implementation of corrective actions for patient safety events.
      (D) Make recommendations to eliminate future patient safety events.
      (E) Review and revise the patient safety plan, at least once a year, but more often if necessary, to evaluate and update the plan, and to incorporate advancements in patient safety practices.
   (2) A reporting system for patient safety events that allows anyone involved, including, but not limited to, health care practitioners, facility employees, patients, and visitors, to make a report of a patient safety event to the health facility.
   (3) A process for a team of facility staff to conduct analyses, including, but not limited to, root cause analyses of patient safety events. The team shall be composed of the facility's various categories of health care professionals, with the appropriate competencies to conduct the required analyses.
   (4) A reporting process that supports and encourages a culture of safety and reporting patient safety events.
   (5) A process for providing ongoing patient safety training for facility personnel and health care practitioners.
(c) For the purposes of this section, patient safety events shall be defined by the patient safety plan and shall include, but not be limited to, all adverse events or potential adverse events as described in Section 1279.1 that are determined to be preventable, and health-care-associated infections (HAI), as defined in the federal Centers for Disease Control and Prevention's National Healthcare Safety Network, or its successor, unless the department accepts the recommendation of the Healthcare Associated Infection Advisory Committee, or its successor, that are determined to be preventable.
### Table 8
Examples of Survey Readiness Activities

<table>
<thead>
<tr>
<th>Activity</th>
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<tbody>
<tr>
<td>Clarify vacation expectations of key staff and leaders based on known survey windows.</td>
</tr>
<tr>
<td>Assign survey roles for key staff duties such as command center operations, space planning, surveyor escorts, or scribes. Determine both a primary and a back-up person for each role and provide an overview of expectations for the role in advance.</td>
</tr>
<tr>
<td>- The escort’s primary function is to remain with the surveyor at all times so the surveyor is not unattended. Escorts develop a relationship with an individual surveyor and should be consistent throughout the survey unless there is not a good match with the surveyor’s personality. Escorts should be matched to surveyors with similar skill sets, for example, a physician with a physician or a nurse with a nurse.</td>
</tr>
<tr>
<td>- Scribes are responsible for documenting the activities of the surveyor and communicating directly with the command center as to those activities.</td>
</tr>
<tr>
<td>- Determine if confidentiality releases, security codes, access cards, or additional name badges will be needed and be sure both scribes and escorts have access to all required clinical areas.</td>
</tr>
<tr>
<td>Update organizational charts that can be attached to the phone lists to facilitate location of key staff during a survey.</td>
</tr>
<tr>
<td>Update lists of phone numbers and create distribution lists for survey communications that include the organizations most common communications methods (e-mail, telephone, or pagers) to facilitate rapid communication during the survey. Set up a digital messaging structures when text pager or phone systems are available.</td>
</tr>
<tr>
<td>Review previous regulatory or accreditation survey reports and the respective corrective action plans to evaluate sustained compliance.</td>
</tr>
<tr>
<td>Ensure that the most current licenses, certificates, patient rights posters, and required signage are posted.</td>
</tr>
<tr>
<td>Assemble required documents to assure easy access to the most current documents.</td>
</tr>
<tr>
<td>Review policies and procedures to ensure all are current.</td>
</tr>
<tr>
<td>Test systems to quickly produce required lists of patients, residents, or clients including scheduled procedures or visits.</td>
</tr>
<tr>
<td>Sweep care areas and departments for outdated policies, procedures, guidelines, order sets, forms, and privilege binders.</td>
</tr>
<tr>
<td>Prepare surveyor orientation materials to prepare for documentation reviews for medical records that introduce electronic records or components of hybrid electronic and paper systems.</td>
</tr>
<tr>
<td>Conduct medical record reviews of open records to ensure compliant records for vulnerable topics. If paper records are in use and a record has been thinned, ensure that the appropriate information is included in the new volume and that the previous volumes are available if requested.</td>
</tr>
<tr>
<td>Test the human resources (HR) file system to ensure access to the complete HR file is readily available on site and that required documentation for education and training is available.</td>
</tr>
<tr>
<td>Check education materials and brochures to ensure availability in the common languages for the populations served by the organization.</td>
</tr>
<tr>
<td>Monitor the environment to ensure that it is clean and compliant with applicable fire and life safety codes.</td>
</tr>
<tr>
<td>If the organization is spread out over a large geographic area, determine whether drivers or shuttles are needed to take surveyors to distant clinical areas. If employees are using their own vehicles, be sure vehicles are clean inside and out.</td>
</tr>
<tr>
<td>Determine surveyor parking plans. Designated spaces close to the main entrance can be identified once a survey has begun. Parking vouchers may be provided. There may also need to be reserved parking spaces for employees driving surveyors or those coming in during the day for key interviews.</td>
</tr>
<tr>
<td>Prepare packets to be given to surveyors upon arrival that include a map of the facility, facility contact list with phone numbers and pagers, organizational chart for the senior leadership team, parking information, and guest ID badges if required. Information or brochures on the local area restaurants and attractions also may be appreciated for after the survey if the team has traveled to your location.</td>
</tr>
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NOT SURE WHICH ONE TO USE>
Figure 1

Readiness Program Requirements

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Figure 2
## CMS-Approved Accreditation Organization Contact Information

<table>
<thead>
<tr>
<th>Organization</th>
<th>Program Type</th>
<th>Address</th>
<th>Contact</th>
<th>Phone Number</th>
<th>E-Mail Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation Association for Ambulatory Health Care (AAAHC)</td>
<td>ASCs</td>
<td>5250 Old Orchard Road Suite 200 Skokie, IL 60077</td>
<td>Villanueva, Michon</td>
<td>847-853-6063</td>
<td><a href="mailto:mvillanueva@aaahc.org">mvillanueva@aaahc.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Gravesmille, Meg Ramahi,</td>
<td>847-853-6073</td>
<td><a href="mailto:mgravemille@aaahc.org">mgravemille@aaahc.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Marcella</td>
<td>847-852-7082</td>
<td><a href="mailto:mramahi@aaahc.org">mramahi@aaahc.org</a></td>
</tr>
<tr>
<td>Accreditation Commission for Health Care, Inc. (ACHC)</td>
<td>HHAs Hospices</td>
<td>4700 Falls of the Neuse Rd Suite 280 Raleigh, NC 27609</td>
<td>Sylvester, Barb Hughes,</td>
<td>919-785-1214</td>
<td><a href="mailto:bsylvester@achc.org">bsylvester@achc.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Matt</td>
<td>919-785-1214</td>
<td><a href="mailto:mhughes@achc.org">mhughes@achc.org</a></td>
</tr>
<tr>
<td>American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)</td>
<td>ASCs OPTs</td>
<td>5101 Washington Street Suite 2F P.O. Box 9500 Gurnee, IL 60031</td>
<td>Baker, Pamela Pearcy,</td>
<td>847-775-1970</td>
<td><a href="mailto:pamela@aaaasf.org">pamela@aaaasf.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Jeff</td>
<td>847-775-1970</td>
<td><a href="mailto:jeff@aaaasf.org">jeff@aaaasf.org</a></td>
</tr>
<tr>
<td>American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)</td>
<td>ASCs CAHs Hospitals</td>
<td>142 East Ontario Street Chicago, IL 60611-2864</td>
<td>Cappiello, Joseph Robins,</td>
<td>312-202-8072</td>
<td><a href="mailto:jcappiello@hfap.org">jcappiello@hfap.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Beverly Zarski, Mike</td>
<td>312-202-8062</td>
<td><a href="mailto:brobins@hfap.org">brobins@hfap.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>312-202-8047</td>
<td><a href="mailto:mzarski@osteotech.org">mzarski@osteotech.org</a></td>
</tr>
<tr>
<td>Community Health Accreditation Program (CHAP)</td>
<td>HHAs Hospice</td>
<td>1275 K Street Suite 800 Washington, D.C. 20005</td>
<td>Duncombe, Terry Farmer,</td>
<td>202-862-3413</td>
<td><a href="mailto:tduncombe@chapine.org">tduncombe@chapine.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Scott</td>
<td>202-862-3413</td>
<td><a href="mailto:kfarmer@chapine.org">kfarmer@chapine.org</a></td>
</tr>
<tr>
<td></td>
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<td><a href="mailto:lscott@chapine.org">lscott@chapine.org</a></td>
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<tr>
<td>DNV Healthcare</td>
<td>Hospitals CAHs</td>
<td>400 Techn Center Drive, Suite 100</td>
<td>Horine, Patrick</td>
<td>513-388-4888</td>
<td><a href="mailto:patrick.horine@dnv.com">patrick.horine@dnv.com</a></td>
</tr>
<tr>
<td>(DNVHC)</td>
<td></td>
<td>Milford, OH 45150</td>
<td>Scott, Darrel</td>
<td>513-388-4862</td>
<td><a href="mailto:darrel.scott@dnv.com">darrel.scott@dnv.com</a></td>
</tr>
<tr>
<td>The Joint Commission</td>
<td>ASCs CAHs HHAs Hospice</td>
<td>One Renaissance Blvd Oakbrook Terrace, IL</td>
<td>Kurtz, Trisha</td>
<td>202-783-6655</td>
<td><a href="mailto:pkurtz@jointcommission.org">pkurtz@jointcommission.org</a></td>
</tr>
<tr>
<td>(JC)</td>
<td>Hospitals Psych Hospitals</td>
<td>60081</td>
<td>Weinberger, Gail</td>
<td>630-792-5766</td>
<td><a href="mailto:gweinberger@jointcommission.org">gweinberger@jointcommission.org</a></td>
</tr>
</tbody>
</table>
### Triggers

<table>
<thead>
<tr>
<th>Issue</th>
<th>Issues</th>
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<tbody>
<tr>
<td><strong>A Failure to protect from abuse.</strong></td>
<td>1. Serious injuries such as head trauma or fractures; 2. Non-consensual sexual interactions; e.g., sexual harassment, sexual coercion or sexual assault; 3. Unexplained serious injuries that have not been investigated; 4. Staff striking or roughly handling an individual; 5. Staff yelling, swearing, gesturing or calling an individual derogatory names; 6. Bruises around the breast or genital area; or Suspicious injuries; e.g., black eyes, rope marks, cigarette burns, unexplained bruising.</td>
</tr>
<tr>
<td><strong>B Failure to Prevent Neglect</strong></td>
<td>1. Lack of timely assessment of individuals after injury; 2. Lack of supervision for individual with known special needs; 3. Failure to carry out doctor’s orders; 4. Repeated occurrences such as falls which place the individual at risk of harm without intervention; 5. Access to chemical and physical hazards by individuals who are at risk; 6. Access to hot water of sufficient temperature to cause tissue injury; 7. Non-functioning call system without compensatory measures; 8. Unsupervised smoking by an individual with a known safety risk; 9. Lack of supervision of cognitively impaired individuals with known elopement risk; 10. Failure to adequately monitor individuals with known severe self-injurious behavior; 11. Failure to adequately monitor and intervene for serious medical/surgical conditions; 12. Use of chemical/physical restraints without adequate monitoring; 13. Lack of security to prevent abduction of infants; 14. Improper feeding/positioning of individual with known aspiration risk; or 15. Inadequate supervision to prevent physical altercations.</td>
</tr>
<tr>
<td><strong>C Failure to protect from psychological harm</strong></td>
<td>1. Application of chemical/physical restraints without clinical indications; 2. Presence of behaviors by staff such as threatening or demeaning, resulting in displays of fear, unwillingness to communicate, and recent or sudden changes in behavior by individuals; or 3. Lack of intervention to prevent individuals from creating an environment of fear.</td>
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<tr>
<td>Issue</td>
<td>Triggers</td>
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<tr>
<td>D Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed.</td>
<td>1. Administration of medication to an individual with a known history of allergic reaction to that medication; 2. Lack of monitoring and identification of potential serious drug interaction, side effects, and adverse reactions; 3. Administration of contraindicated medications; 4. Pattern of repeated medication errors without intervention; 5. Lack of diabetic monitoring resulting or likely to result in serious hypoglycemic or hyperglycemic reaction; or 6. Lack of timely and appropriate monitoring required for drug titration.</td>
</tr>
<tr>
<td>E Failure to provide adequate nutrition and hydration to support and maintain health.</td>
<td>1. Food supply inadequate to meet the nutritional needs of the individual; 2. Failure to provide adequate nutrition and hydration resulting in malnutrition; e.g., severe weight loss, abnormal laboratory values; 3. Withholding nutrition and hydration without advance directive; or 4. Lack of potable water supply.</td>
</tr>
<tr>
<td>F Failure to protect from widespread nosocomial infections; e.g., failure to practice standard precautions, failure to maintain sterile techniques during invasive procedures and/or failure to identify and treat nosocomial infections</td>
<td>1. Pervasive improper handling of body fluids or substances from an individual with a infectious disease; 2. High number of infections or contagious diseases without appropriate reporting, intervention and care; 3. Pattern of ineffective infection control precautions; or 4. High number of nosocomial infections caused by cross contamination from staff and/or equipment/supplies.</td>
</tr>
<tr>
<td>G Failure to correctly identify individuals.</td>
<td>1. Blood products given to wrong individual; 2. Surgical procedure/treatment performed on wrong individual or wrong body part; 3. Administration of medication or treatments to wrong individual; or 4. Discharge of an infant to the wrong individual.</td>
</tr>
<tr>
<td>Issue</td>
<td>Triggers</td>
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<tr>
<td>H Failure to safely administer blood products and safely monitor organ transplantation.</td>
<td>1. Wrong blood type transfused; 2. Improper storage of blood products; 3. High number of serious blood reactions; 4. Incorrect cross match and utilization of blood products or transplantation organs; or 5. Lack of monitoring for reactions during transfusions.</td>
</tr>
<tr>
<td>I Failure to provide safety from fire, smoke and environment hazards and/or failure to educate staff in handling emergency situations.</td>
<td>1. Nonfunctioning or lack of emergency equipment and/or power source; 2. Smoking in high risk areas; 3. Incidents such as electrical shock, fires; 4. Ungrounded/unsafe electrical equipment; 5. Widespread lack of knowledge of emergency procedures by staff; 6. Widespread infestation by insects/rodents; 7. Lack of functioning ventilation, heating or cooling system placing individuals at risk; 8. Use of non-approved space heaters, such as kerosene, electrical, in resident or patient areas; 9. Improper handling/disposal of hazardous materials, chemicals and waste; 10. Locking exit doors in a manner that does not comply with NFPA 101; 11. Obstructed hallways and exits preventing egress; 12. Lack of maintenance of fire or life safety systems; or 13. Unsafe dietary practices resulting in high potential for food borne illnesses.</td>
</tr>
<tr>
<td>Issue</td>
<td>Triggers</td>
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<tr>
<td>Failure to provide initial medical screening, stabilization of emergency medical conditions and safe transfer for individuals and women in active labor seeking emergency treatment (Emergency Medical Treatment and Active Labor Act).</td>
<td>1. Individuals turned away from ER without medical screening exam; 2. Women with contractions not medically screened for status of labor; 3. Absence of ER and OB medical screening records; 4. Failure to stabilize emergency medical condition; or 5. Failure to appropriately transfer an individual with an unstabilized emergency medical condition.</td>
</tr>
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