

# Top Risks for Healthcare 2021

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Healthcare organizations continually face difficult decisions about how they focus time, energy, and dollars to avoid undue risk exposure.

To manage this environment of increasing risks and limited resources, healthcare internal audit departments must align their risk assessments and resulting internal audit plans to the areas most critical to achieving organizations' strategic goals and business objectives and maintaining compliance with critical regulatory and other requirements. This risk-based approach focuses on the most critical risk areas and suggests less effort, if any, be applied to low-risk areas. The better the alignment between the internal audit plan and the most critical organization risks, the greater return on risk achieved for an organization's internal audit investment.

# Crowe's Top 20 Risks

## Are these on your radar?

Crowe has identified the top risks facing healthcare organizations in 2021 using input from:

- Executive management and board members at some of the largest health systems in the U.S.; and
- Crowe risk assessments conducted at nearly 300 health systems and hospitals, and hundreds of other healthcare provider clients, in 2020 and 2021.



# Clinical:

**Mental Health** - Risks include missed or incomplete suicide risk screening and mental health assessments, unsafe patient environment that is not ligature-resistant, and untimely access or limited availability to services resulting in patient and staff harm and delayed or inappropriate care delivery.

**Audits for Consideration:**

- Environmental and Ligature Risk Assessment
- Mental Health Assessment and Suicide Risk Screening
- Timely Access to Mental Health Services

**Clinical and Operational Compliance** – Risks include noncompliance with regulatory and accrediting standards of care or industry guidelines resulting in loss of deemed status or accreditation, decreased quality, and financial loss.

**Audits for Consideration:**

- Laboratory Standards Compliance (CLIA/CAP/COLA)
- National Patient Safety Goals Alignment
- Ambulatory Practice Tests and Referral Management

**Pharmacy** - Key risks related to lack of compliance with the 340B Drug Pricing Program statute resulting in manufacturer repayments or removal from the 340B Program, ineffective drug diversion monitoring programs resulting in risk of controlled substance diversions and related fines from government agencies, and inadequate monitoring of opioid prescriptions resulting in prescribing rates outside of regulatory guidelines and patient harm.

**Audits for Consideration:**

- 340B Program Compliance Audit
- Drug Diversion Audit
- Opioid Prescribing Analysis and Monitoring Assessment

**Patient Safety** - Risks include noncompliance with regulatory guidelines and evidence-based practices for patient safety including environment of care, infection control, and safe handling and movement of patients. Noncompliance can result in patient harm, decreased quality-based scores and medical reimbursement.

**Audits for Consideration:**

- Surgical Safety and Surgical Suite Disinfection
- Device Sterilization and Disinfection
- Infection Prevention (Hospital-acquired Conditions)

**Case/Care Management** - Risks include noncompliance with CMS Conditions of Participation (CoPs), incorrect admission status, inadequate discharge planning and weak transitions of care, which could impact quality and patient safety, leading to extended length of stay and/or avoidable readmissions.

**Audits for Consideration:**

- Compliance with CMS CoPs.
- Appropriate Patient Status Assignment (Inpatient vs. Observation)
- Discharge Planning and Transitions of Care

# Regulatory Compliance:

**Physician Contracting and Compensation** - Risks include violating federal fraud and abuse statutes (e.g., Stark, false claims, and anti-kickback statutes) through payments to physicians without a contract, in excess of contractual amounts and/or above fair market value. Other risks include physicians utilizing hospital space without appropriate lease or compensation to the health system, recruitment arrangements that do not meet regulatory requirements, and failure to monitor contract and recruitment arrangement terms.

**Audits for Consideration:**

- Physician Payments
- Physician Contracting Process, including Recruitment and Leases

**Advanced Practice Professionals (APPs) Compliance** - Risks include non-compliance with government regulations and payer contract requirements around clinical documentation and billing for services performed by both the APP and the physician. Scope of practice and supervision (if applicable) may not meet facility or medical group by-laws and state-specific requirements.

**Audits for Consideration:**

- APP Services Documentation and Billing Compliance
- Compliance with Collaborative Agreements and Supervision Requirements
- Scope of Practice Alignment with By-Laws and State Requirements



# Financial / Operational:

**Emergency Preparedness and Business Continuity (Non-IT)** - Risks include being unprepared for a large influx of patients or being unable to continue operations in the event of a natural or human-created disaster. Operational risks are compounded by regulatory concerns (CMS, Joint Commission, and state authority regulations for emergency preparedness) and the need to keep patients and staff safe from harm during a disaster.

**Audits for Consideration:**

- CMS Emergency Preparedness
- Emergency Management (Patient and Staff Safety) Processes
- Business Continuity Planning (IT and Non-IT)

**Vendor Management** - Risks include vendors' failure to meet contracted performance requirements and financial terms, billing for services not provided, failure to comply with legal and regulatory requirements, patient safety exposure due to unsecured medical devices or ineffective vendor employee screening, reputational and financial risk due to vendor security or privacy breaches and lack of a Business Associate Agreement.

**Audits for Consideration:**

- Vendor Contracting
- Vendor Management Process including IT Risk Management

**Liquidity and Margin Pressure** - Risks include increased costs due to governmental efforts to raise the minimum wage or effects of competition, decreased revenue due to healthcare workers exiting the industry post-COVID, cost of extra staff, protective equipment and supplies to ensure continued patient and staff safety in post-pandemic environment, and inability to adequately support and defend pandemic relief funds received from State and Federal sources.

**Audits for Consideration:**

- Bond Covenant Compliance
- Scheduling and Productivity
- Pandemic Relief Fund Audit Preparedness (e.g., CARES Act, FEMA, etc.)

**Revenue Cycle** - Risks include noncompliance with government regulations and payer contract requirements resulting in lost reimbursement, fines and exclusion from participation in governmental programs. Inefficiencies in revenue cycle operations and performance could result in delayed or reduced cash flow, unnecessary overhead, negative patient experience, and reduction in community benefit.

**Audits for Consideration:**

- Revenue Cycle Process Effectiveness
- Price Transparency Rule Compliance
- Coding and Clinical Documentation and Medical Necessity

**Competition** - Due to competitive challenges from a broad range of entrants, both traditional (e.g., urgent cares, surgical centers) and non-traditional (e.g., large retail, technology companies, private equity), risks include increased challenges in recruiting and retaining hospital staff, clinicians and management personnel, reduced inpatient and outpatient volumes, reduced financial performance, and loss of market share.

**Audits for Consideration:**

- ERM Process Assessment
- Joint Venture / Continuum of Care Strategy Assessment

# Emerging:

**Telemedicine** - Risks include non-compliance with government and commercial payer requirements for documentation and billing of telehealth services resulting in denied claims and lost reimbursement, as well as cyberattacks on telemedicine technology resulting in system failure and disruption impacting quality of care, patient experience and potential HIPAA privacy violations.

## **Audits for Consideration:**

- Compliance with Documentation and Billing Requirements for Telehealth Services (e.g. modifiers, place of service, consents)
- IT Audit and Cybersecurity Assessment over Telehealth Platform and Devices
- Cybersecurity Assessment over Network and Unified Communications Supporting Telehealth

**Remote Workforce** - COVID-19 required most organizations to quickly implement work from home capabilities for their administrative workforce resulting in less secure devices and network connections, resulting in increased privacy and security risk.

## **Audits for Consideration:**

- Assessment of Remote Access
- Employee Home Office Storage and Printing Functionality
- Remote Workforce IT Controls

**Cybersecurity** - Risks include the increasing threat of ransomware, insecurity of biomedical and IoT (Internet of Things) devices, a significant increase in email phishing (and spear phishing) attacks and exposure of home offices and networks.

## **Audits for Consideration:**

- Ransomware Preparedness and Response
- Biomedical and IoT Program Security
- Cybersecurity Assessment

**Social Determinants of Health (SDOH) and Health Equity Gaps** - Risks include ineffective mechanisms to track SDOH and lack of community access to healthcare services resulting in the inability to develop comprehensive healthcare plans, poor health outcomes and increased costs.

## **Audits for Consideration:**

- SDOH Program Assessment
- Data Analysis for Preventative Service/Screening and Population Health
- SDOH-Related Performance Improvement

**Workforce Recruiting and Retention** - Risks include pandemic-related employee burnout leading to increased leaves of absence, accelerated retirements and clinical staff leaving the healthcare industry, increased competition for workers from non-healthcare businesses (e.g., large tech and retail) offering higher wages, less stressful environment and better benefits, scarce availability of skilled clinicians and lack of ability or commitment in identifying diverse candidates.

**Audits for Consideration:**

- Critical Department Staffing Levels
- Recruiting

**Staff Safety** - Due to rising levels of attacks on hospital staff by patients and visitors, risks include mental or physical harm to workers, financial losses due to worker compensation claims, increased overtime and use of temporary staff, and litigation, declining staff morale, and increased difficulty in recruiting and retention.

**Audits for Consideration:**

- Regulatory Safety Compliance
- Hospital Safety Protocols
- Facility Security and Access Controls

**Acute Care at Home Program** - Patients admitted into the program may not meet qualifications for an acute care at home setting. Care delivered for patients at home may not align with standards of care requirements for an acute level of care and may impact care quality and patient safety. Hospitals may not be able to fulfill staffing and technology requirements which can impact patient experience. Documentation and billing of services performed may not comply with government and payer requirements.

**Audits for Consideration:**

- Program Admission and Qualification Process
- Program Oversight for Standards of Care, Quality, and Patient Safety and Experience
- Documentation and Billing

**CARES Act Provider Relief Funds and Federal Grant Compliance** - Risks include recoupment of pandemic related funds due to inadequate support of healthcare related expenses and/or lost revenue calculations and non-compliance with terms and conditions for use of the funds.

**Audits for Consideration:**

- Assessment of Pandemic Reporting
- Special Project: Preparation of Pandemic Fund Submission(s)
- OIG Audit Preparedness







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