

Top risks for healthcare 2021

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

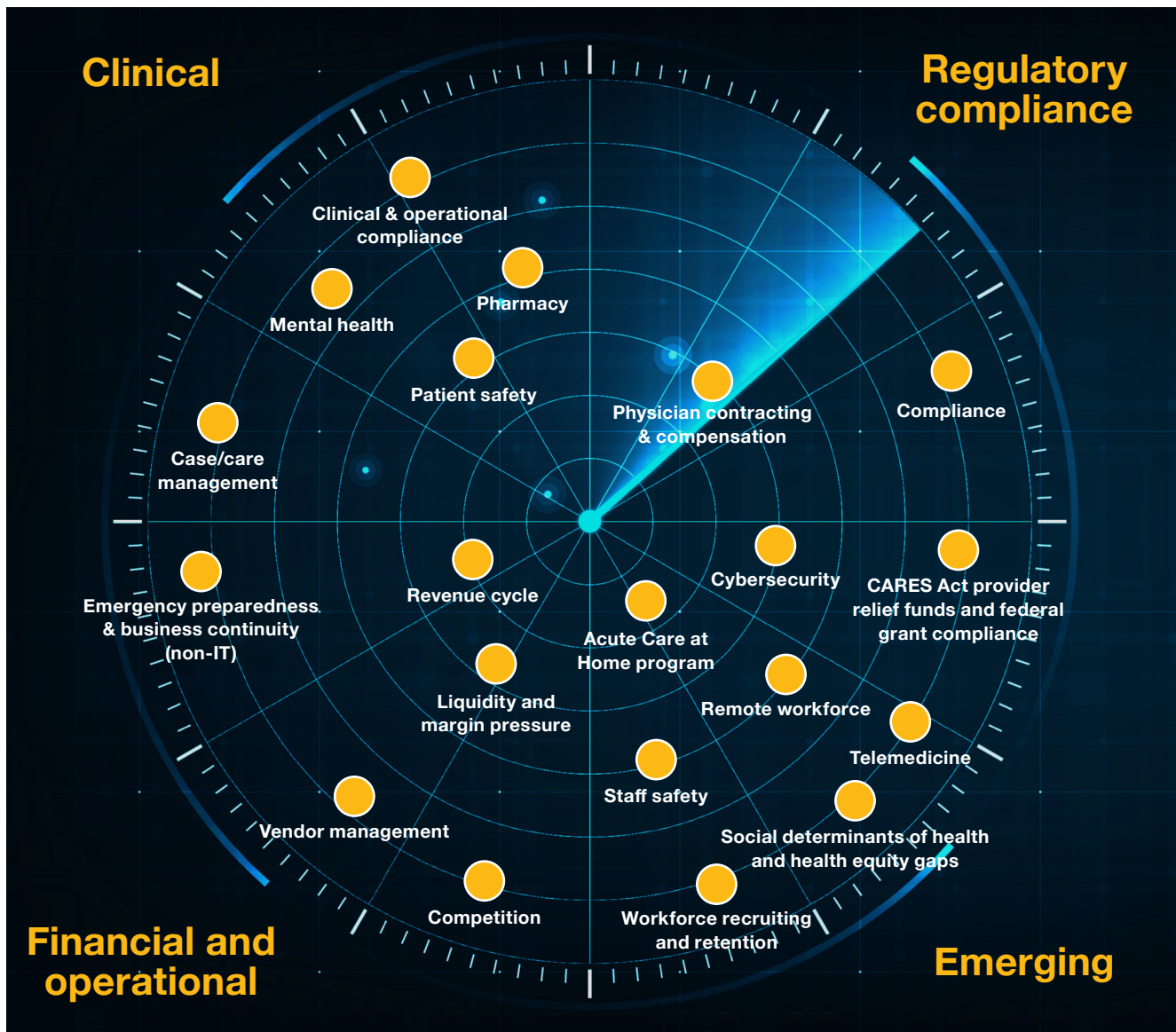
To manage this environment of increasing risks and limited resources, healthcare internal audit departments must align their risk assessments and resulting internal audit plans to the areas most vital to achieving organizations' strategic goals and business objectives, while maintaining compliance with 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 the return on risk for an organization's internal audit investment.

The 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.
- Crowe risk assessments conducted at nearly 300 health systems and hospitals as well as hundreds of other healthcare provider clients' data, in 2020 and 2021.

Risks fall into four areas: clinical, regulatory compliance, financial and operational, and emerging. In addition to describing these risks, we suggest related audits to be considered.



Clinical risks

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 or 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 (Clinical Laboratory Improvement Amendments, College of American Pathologists (CAP), Commission on Office Laboratory Accreditation)
- National Patient Safety Goals alignment
- Ambulatory practice tests and referral management

Pharmacy

Key risks are 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 reduced 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 Centers for Medicare & Medicaid Services (CMS) conditions of participation (CoPs), incorrect admission status, inadequate discharge planning, and weak transitions of care, which could affect quality and patient safety, leading to extended length of stay and avoidable readmissions.

Audits for consideration:

- Compliance with CMS CoPs
- Appropriate patient status assignment (inpatient versus observation)
- Discharge planning and transitions of care

Regulatory compliance risks

Physician contracting and compensation

Risks include violating federal fraud and abuse statutes (such as Stark Law and false claims and anti-kickback statutes) through payments to physicians without a contract, in excess of contractual amounts, or above fair market value. Other risks include physicians using hospital space without appropriate lease agreement with 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 providers (APPs)

Documentation and billing compliance

Risks include noncompliance with government regulations and payer contract requirements related to 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 bylaws 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 bylaws and state requirements

Financial and operational risks

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, cost of protective equipment and supplies to ensure continued patient and staff safety in a post-pandemic environment, and inability to adequately support and defend pandemic relief funds received from state and federal sources such as the *Coronavirus Aid, Relief, and Economic Security Act* (CARES Act) and the Federal Emergency Management Agency.

Audits for consideration:

- Bond covenant compliance
- Scheduling and productivity
- Pandemic relief fund audit preparedness

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 competition from a broad range of entrants, both traditional (for example, urgent cares, surgical centers) and nontraditional (for example, large retail facilities, technology companies, private equity-backed companies), 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:

- Enterprise resource management process assessment
- Joint venture and continuum of care strategy assessment

Emerging risks

Telemedicine

Risks include noncompliance 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 affecting quality of care, patient experience, and potential HIPAA privacy violations.

Audits for consideration:

- Compliance with documentation and billing requirements for telehealth services (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 as well as 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 increases in ransomware threats, biomedical and IoT (internet of things) device insecurity, 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, and increased competition for workers from nonhealthcare businesses (for example, large tech and retail companies) offering higher wages, less stressful environment, and better benefits; scarce availability of skilled clinicians; and lack of ability or commitment to identify 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 workers' compensation claims, increased overtime and use of temporary staff, 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 Hospital Care at Home program

Patients admitted into the program might not meet qualifications for an acute care at home setting. Care delivered for patients at home might not align with standards of care requirements for an acute level of care and may affect care quality and patient safety. Hospitals might not be able to fulfill staffing and technology requirements, which can affect patient experience. Documentation and billing of services performed might 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 or lost revenue calculations and noncompliance with terms and conditions for use of the funds.

Audits for consideration:

- Assessment of pandemic reporting
- Preparation of pandemic fund submission(s)
- Office of Inspector General audit preparedness



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