During 2015, the healthcare risk landscape continued to increase in complexity. Although many areas remained consistent, new issues opened healthcare organizations to complicated areas of exposure. Identifying, assessing and addressing those vulnerabilities will help organizations achieve their goals in the future.

To that end, CHAN Healthcare analyzed information from risk assessments conducted for clients between January and June 2015. The data included nearly 4,000 risks in 130 processes, and it came from analysis of more than 250 hospitals and other healthcare entities. Two significant factors used in evaluating risk were strategic and business impact and business environment complexity.

From the data, 20 significant risks emerged; these exposure points provide an important industry benchmark for internal auditors. By comparing their audit plans to CHAN’s analysis, internal auditors can determine whether they have addressed the top health system risks or if they need to revisit their plans.

Areas of urgency
For many healthcare systems, changes in several realms—from technology to regulatory—brought new issues to the forefront. With these emerging issues come risk and potential challenges. Areas drawing broad and increased focus include the following.

Clinical excellence
With the growing number of clinical initiatives linked to reimbursement, patient safety and quality of care are top priorities for healthcare organizations. Given that hospitals and health systems are rewarded not merely for doing well but for doing comparatively well, benchmarking against other providers is very important.

Data on care delivery performance (also known as quality measures) are reported in a variety of ways. Clinical risks identified include monitoring the implementation of evidence-based practices, increasing the reliability of clinical processes, and adhering to regulatory standards for care delivery. Healthcare organizations should consider adding...
clinical expertise to the internal audit function to better address these critical areas.

ICD-10 transition
For the past several years, healthcare organizations have been preparing to implement the significant coding and process changes needed to support the transition to International Classification of Diseases 10th revision (ICD-10) code sets. With the October 1, 2015, implementation date past, healthcare organizations are now learning whether the training of clinicians and coders has paid off, whether they are able to submit claims with the new codes and whether payers are able to process claims.

To minimize potential negative impacts to operations and revenue, organizations should consider processes to identify and resolve any gaps in implementation. Thus, many hospitals and health systems are monitoring coding, claims submission and denials with increased urgency. Internal audit can assist in identifying gaps in these areas through process-focused audits of the revenue cycle.

340B Drug Pricing Program
Although healthcare organizations can realize major savings through the 340B Drug Pricing Program, noncompliance with complex regulations can jeopardize the savings if program integrity is not maintained.

Organizations that are succeeding in this area have taken a multidisciplinary approach by convening pharmacy, compliance, IT, finance and leadership staff. Together, they can examine the published rules and monitor their organization's programs by testing transactions to ensure they are processed as intended.

The internal audit department may play a role in conducting annual independent audits, as the Health Resources and Services Administration (HRSA) suggests for contract pharmacy arrangements. Best practice is to perform an annual independent audit on the hospital side as well.

Accountable care organizations
Healthcare organizations have become increasingly engaged in accountable care organizations (ACOs) and clinically integrated networks. With this, they assume the risk of managing the health of an entire population. For organizations participating in the Medicare Shared Savings Program, complex regulations affect clinical, IT and compliance functions. Although ACOs vary significantly, the internal audit department can provide insight into identifying and managing related risks.

Cybersecurity
Concerns over cybersecurity risks have understandably exploded based on the sharp increase in the frequency of and media focus on network security breaches and cyberattacks. The healthcare industry is particularly vulnerable based on the sheer number of devices that health systems and clinicians use.

Furthermore, cybercriminals can reap a larger profit from health data. Cybersecurity experts maintain that stolen medical data is valued at 10 times the amount of stolen credit card information.¹ Healthcare organizations need greater insight into vulnerabilities and ways to minimize their exposure to threats. They also need strategies for reducing the financial, reputational and regulatory impacts of an incident if systems are breached.

Healthcare organizations should consider adding clinical expertise to the internal audit function.

Internal auditors are uniquely positioned in the organization to be able to assess security design and operational controls, affording management much-needed visibility into potential vulnerabilities. Through in-depth knowledge of leading security control practices, the internal audit department can advise management on needed process

¹ www.reuters.com/article/us-cybersecurity-hospitals-idUSKCN0HJ21120140924
enhancements and other strategies to minimize the negative impact of a system breach.

**Meaningful use**
Meaningful use (MU) is a high-risk area for both hospitals and eligible providers, due to the significance of the funds tied to MU criteria. Many healthcare systems now have been audited by the Centers for Medicare and Medicaid Services (CMS) at least once, and organizations are seeking insight into readiness to pass additional compliance audits successfully.

**Cybersecurity experts maintain that stolen medical data is valued at 10 times the amount of stolen credit card information.**

Even though the continuance of the meaningful use program is uncertain, any organization that has received funds under the program remains subject to regulatory audits. Audit assistance should be provided in the window prior to attestation in order to rectify potential issues in advance. In addition, the internal audit department can perform post-attestation compliance assessments against known CMS audit criteria. These can help organizations address documentation proactively and address process gaps to improve readiness for a potential CMS examination.

**Areas of ongoing risk**
While CHAN’s risk assessment analysis pinpointed several new issues, the bulk of the data identified areas that have been a consistent focus for clients from year to year. Those include the following.

**IT application implementation**
This area of significant risk is related to the continued implementation and enhancement of electronic health record (EHR) technology as well as other key business and clinical systems.

Even within a single organization, clinicians and staff may use several different platforms. As a result, data and processes that move from one department to another increase risk. Pre-implementation audits can help identify roadblocks to meeting timeline and budget constraints.

A primary area of focus for internal audit is the overall project management process for the IT application implementation effort. Also, it’s important to identify risks during the phases before implementation, such as integrated testing risks reported as having been mitigated, adequate training tied to system access in production, identification of new operational processes before implementation of systems, and the cutover plans to implement the systems along with the team necessary to address and resolve issues after go-live.

**Physician contracting**
Healthcare remains focused on physician alignment, and physician arrangements continue to be highly complex, making physician contracting an ongoing area of risk. Noncompliance with the Stark Law and other anti-kickback and fraud and abuse statutes could make organizations susceptible to litigation, fines and penalties.

As hospitals become more innovative in structuring arrangements with physicians, internal controls must be in place to monitor those contracts. Without such monitoring, healthcare organizations might be unaware that they are violating regulations but will still be held accountable. Often, robust physician contracting policies and procedures have been put in place, and the internal audit department can assist in testing whether these procedures are being followed consistently.

**Billing and collection**
Many healthcare organizations are taking significant steps to consolidate the revenue cycle. Those that have centralized their process run the risk that a potential breakdown in one point of the cycle will affect the entire organization at once.

In addition to making operational and workflow changes because of centralization or outsourcing, healthcare organizations face a complex and challenging process to produce a timely, error-free claim that can be quickly adjudicated and paid. The heightened risk in this area reflects rising concerns over significant changes in billing and collection functions. Internal auditors can help to determine that controls are working as intended when changes are being made to consolidate revenue cycle processes that significantly affect reimbursement.

**Physician compensation**
Physician compensation is fraught with regulatory restrictions, and internal control weaknesses can lead to significant risk. Again, Stark Law and anti-kickback, fraud and abuse statutes are of particular concern, possibly resulting in significant financial, legal and reputational risks.

An additional consideration is the appropriate classification of physicians under Internal Revenue Service tax filing requirements. Testing calculations and reviewing compliance with documented policies and procedures
pertaining to physician compensation are two of the ways the internal audit department can assist.

**Third-party vendor oversight**
While outsourcing certain functions to third parties with specialized expertise offers benefits, healthcare organizations ultimately are responsible for those functions. Accountability cannot be outsourced. Neglecting to exercise appropriate oversight intensifies risk points and opens the door to potential noncompliance. Audits in this area should focus on verifying that vendors perform in accordance with agreed-upon terms and that payments are made in accordance with contract provisions.

**Denials management**
Denials can occur for a variety of reasons, including billing for noncovered services, registration errors and incorrect billing codes. Denials slow the cash flow process and often result in time-consuming resolution work efforts. Healthcare systems must establish internal controls to identify, classify, track and correct denials in a timely manner to minimize their financial and operational impact. The internal audit department’s expertise in root cause analysis can assist organizations in determining where gaps are in the denials management process.

**Charge capture**
With the changes resulting from initiatives such as EHR implementation and the transition to ICD-10, charge capture is a consistent area of concern. Particularly with the specificity of new codes, healthcare systems anticipate initial challenges with the way charges are generated by providers, queried by coders, and processed between systems. The resulting delays may make it difficult for some organizations to meet their revenue recognition goals. Internal audits in this area can help pinpoint weaknesses and implement corrections.

**Physician practice revenue cycle**
Organizations continue to acquire physician practices, resulting in revenue cycle risks as significant processes are consolidated. Internal audits in this area have identified a lack of formal process documentation, inadequate staff training, and issues with accountability. In addition, many practices have implemented new systems, resulting in increased risk due to workflow and process changes and potential inefficiencies.

**HIPAA**
Governance and management teams remain sensitive to potential vulnerabilities and the reputational and financial risks related to a possible security or privacy incident. The Office for Civil Rights (OCR) is continuing to place additional emphasis on enforcement of the Health Insurance Portability and Accountability Act (HIPAA) through expansion of its audit program. Healthcare organizations are interested in where they stand with respect to compliance audit readiness.

Managing and maintaining the privacy and security of protected health information also has become increasingly challenging due to the escalation in adoption of mobile devices, network-connected medical devices and telehealth initiatives. Through periodic audits of HIPAA compliance, internal auditors can help identify and close gaps in control implementation that could result in a security or privacy breach.

In addition, internal audits may be focused on evidence of controls and effective process documentation, and on assessing the organization’s ability to meet expectations in the event of an OCR HIPAA compliance audit.

**Patient access**
The revenue cycle begins with patient access, making this a crucial area of focus for providers. Given that patient satisfaction is now a component of quality measurement and reporting, healthcare organizations must assess the effectiveness of patient access points. Internal audit can help identify weak controls in patient access, which can result in billing and patient accounting issues, lost revenue and poor patient and physician satisfaction.

**Financial statement close process**
This area has been a consistent focus for healthcare systems from year to year. Accurate and timely financial reporting is required of all healthcare organizations, and management and governance teams continue to engage the internal audit department in identifying and addressing risks as part of a strong financial integrity program.

**Medication management and drug diversion**
Inadequate controls over dispensed medication, especially controlled substances, can have significant financial, compliance, patient care and reputational impacts for all healthcare systems. Pharmacists and care providers share
responsibility for preventing prescription drug abuse and diversion by establishing controls over ordering, dispensing and administering as well as maintaining inventory records and diversion-monitoring processes.

**Accountability cannot be outsourced.**

To reduce risks in this area, hospitals and providers should evaluate and update procedures used to identify repeat opioid-seeking patients, and to manage notification of other providers. This is particularly relevant to patients with repeat visits to the emergency department. Data analytics can be used by internal auditors to identify anomalies that may uncover instances of drug diversion.

**Coding**

Coding accuracy continues to be a high-risk area for healthcare organizations due to the diversity of reimbursement models across the healthcare continuum, complexity of coding rules and regulations, and scrutiny by the Office of Inspector General (OIG) and other government audit entities.

Accurate coding of services provided is core to timely revenue recognition. The complexity surrounding coding rules varies across specialties, and the potential for denials, penalties, sanctions and lost revenue if regulatory requirements are not met is significant. To prevent claims denials and mitigate government audit scrutiny, robust audit and monitoring of the coding function is essential in healthcare’s highly regulated and constantly changing environment. It also is an essential element of an effective compliance program, as recommended by the OIG.

**Supply chain and inventory management**

Healthcare organizations continue to look for ways to more effectively manage their inventory, minimize inventory costs and support patient care. While purchasing continues to be an area of specific concern, auditors may get involved in reviewing risks related to managing consignment and other inventory as well as in the consolidation and outsourcing of inventory management functions.

**Summary**

By comparing their current plans with these risk areas, internal auditors can make a positive impact on their organizations. When potential gaps in coverage are identified, significant exposure points—as well as the internal audit department’s ability to address the risks—can be communicated to management and the governance function so the organization can mitigate existing risk and anticipate future concerns. NP