Healthcare Compliance & Reimbursement

Investing in Compliance

Inside

Understand the value of moving from reactive compliance to proactive continuous improvement.

The State of Healthcare Compliance

The primary mission of every health care organization is to provide high-quality, cost-effective services to patients, families, members, and their communities. In accomplishing this mission, many organizations view regulatory compliance as a necessary evil that federal and state governments impose upon them. Those organizations that operate with high integrity view their compliance obligations as a burden they must bear to protect the world against a few bad apples. The stresses imposed by the current regulatory environment promote a comply-or-see-yourselves-on-the-evening-news mentality and fuel resentment among many senior leaders who regard compliance as an obligation rather than a valuable asset.

Nevertheless, Health & Human Services Office of Inspector General (OIG) and the Department of Justice expect health care organizations to maintain compliance programs, and federal sentencing guidelines reinforce that goal. The quality of an organization's compliance program can make the difference between a mistake and reckless disregard, which can invite massive fines and criminal prosecution. With the Recovery Audit Contractor (RAC) program identifying over $10B in payment corrections (overpayments & underpayments) since its inception[1,2], reported Protected Health Information (PHI) breaches growing exponentially, and health care reform and fraud prevention, governmental scrutiny will not abate. Whether or not such scrutiny is justifiable, it is here to stay, and there simply is no hiding from it.

[1] CMS published figure in single updated report dated March 4, 2016 (National Program Total Corrections) at the following site https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Program-Reports.html

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Program-Reports.html

Compliance programs in health care have evolved in response to the OIG's Compliance Program Guidance, federal sentencing guidelines, and certain financial-control elements of the Sarbanes-Oxley Act. Most compliance programs consist of seven elements:

1. high-level oversight;
2. written standards of conduct, policies, and procedures;
3. education and training;
4. auditing and monitoring;
5. a communication process;
6. a disciplinary process;
7. and a process for responding to detected offenses.

Furthermore, federal sentencing guidelines now recommend implementation of annual risk assessments that cover all areas of the organization (the eighth element). All these requirements, in combination with the multitude of new regulations issued each year, means that without effective tools, there is no way even a large compliance team can effect change, conduct oversight activities, and keep up to date.

Without a comprehensive set of tools comparable to those used by accounting, purchasing, finance, billing, and scheduling, compliance officers are left to construct their own War and Peace-size regulatory compendia of conflicting government transmittals, newsletters, and guides. They also rely on costly outside resources and homegrown tools. These resources do help and are valuable, but they are not enough for ongoing and day-to-day management of the compliance program, and they do not integrate understanding, experience, and knowledge into the daily process.

New emphasis on quality of care and the increasing need to protect against financial, operational, and reputational risk have made it even more crucial to elevate compliance beyond one person's job to a top-down governance-based approach that needs to be instilled throughout the enterprise as a "culture of compliance." Add to that the increased security burden placed on the enterprise by the necessary availability of patient data, the unavoidable issue of "bring your own device" or "BYOD," and the increased enforcement of HIPAA violations and it becomes clear that the effectiveness of your compliance program will have a direct impact on the organization's operational, financial, and reputational risk and, ultimately, the bottom line.

> *"Just because a hospital is not getting record requests, don't assume that you are not being audited and losing money."*
>
> *— Elizabeth Lamkin, a partner at PACE Healthcare Consulting*

Many organizations use paper processes that are cumbersome and labor intensive. Others have homegrown solutions that are well thought-out and meet certain needs, but they are typically siloes of information that:

- Do not integrate all the elements of an effective compliance program in one place;

- Do not leverage a network of organizations that use the same tools with a centralized development and management team; and

- Do not integrate into the daily work flow and are not the enterprise-wide solutions necessary to create a culture of compliance.

Without clear, real-time visibility into the risk and compliance stance of your organization, you are making decisions based on incomplete or inaccurate information. If you are to be held responsible for the activities within your enterprise, you should have the insight you need to proactively manage against your regulatory stance.

The OIG work plan varies from year to year and suggests areas of focus but does not cover all aspects of the regulations and issues with which organizations are supposed to comply or those that should be monitored.

The Emergence of Evidence-Based Compliance

The world of compliance is changing. Management teams, beginning to embrace compliance as they have embraced Lean Six Sigma quality methodologies, are discovering that compliance is good for operational outcomes. A consistent and institutionalized compliance program has a positive impact on business processes, accountability, governance, and, ultimately, the bottom line. And in the event of a mistake—or worse yet, a bad apple—a well-developed compliance program enables the organization, its management team, and board to withstand the heat of an investigation.

Wolters Kluwer maintains that an effective compliance solution equates to a system within which regulations, generally accepted business practices, and organizational wisdom are integrated with risk assessment, management, and tracking tools to proactively drive evidence-based compliance. By embedding compliance into daily practice, the management team and board can get a clear picture of the status of compliance across the organization as well as make compliance a part of the organizational culture.

There are several features of a compliance program, regardless of what systems or mechanisms are deployed to manage it, that make it evidence-based:

- A program that involves all areas of the organization at the department, subject, and process levels.
- Risk assessment tools and questions directly linked to the specific regulatory citations or source material from which they are derived.
- Work plans driven specifically from the risk assessment.
- Compliance plans that are pushed into the daily workflow through publicly accessible

"Every organization should integrate information, processes, and systems to deliver metrics that support the ability of the business to achieve objectives while addressing uncertainty and acting with integrity. Measuring and analyzing compliance and ethics efforts ensures a well-run capability, supports organizational integrity, and delivers information for strategic and operational decision-making that is essential to organizational performance."[3]

— Open Compliance and Ethics Group (OCEG)

policies and procedures, email reminders, task management tools, and reporting.

- Communications management and tracking tools.
  - Hotlines, letters, phone calls, and conversations that are integrated into tools for education tracking, disciplinary action management, and auditing for a closed-loop system.
- Billing and reimbursement compliance tools.
  - MAC correspondence tracking and integrated coding tools such as eCodebooks, payment calculators, LCDs/NCDs, fee schedules, crosswalks, and similar capabilities.
- Regulatory, reimbursement, and legal content databases and tools.
  - Integrated with the compliance platform to support daily alerts, accurate billing, auditing, and oversight of the program.

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[3]   Integrated Compliance & Ethics Metrics, OCEG.

An evidence-based compliance program can improve processes, reduce risk, and improve the bottom line of any organization. Commonly referred to as GRC, which stands for Governance, Risk, and Compliance, this holistic approach to embedding a complete enterprise-wide culture of compliance has been adopted as the best practice approach by all major highly regulated industries, including finance and energy.

The Value of an Evidence-Based Compliance Program

Utilizing GRC to build a culture of compliance delivers a compelling return on investment. Particularly in highly regulated, high-risk industries such as health care, the alternatives are often slow or no reimbursement, fines, penalties, lawsuits, public censure, and even criminal prosecutions and convictions.

Financial Risk: Claims Audits

Third-Party Claims Audits Risk

Utilizing data from the 2014 CMS report to Congress regarding RAC program, divide third-party claims audit and appeals denials and collected overpayments totaling $2.5B by 4780 total hospitals[8] to arrive at a figure of $523,000 average annualized risk per US hospital.

The growth of the RAC program alone—from $92M (FY2010) to $2.5B (FY2014) in payment corrections (overpayments & underpayments)[4]—is a substantive incentive to invest in compliance in order to offset the high financial risk to the organization. While the industry experienced a decrease in specific RAC results in FY2015 (to $440M)[5], the Department of Justice reported government health care recoveries of $2.4B in FY2015,[6] not to mention increased non-RAC audit activity providers are experiencing from government and private payers. Regardless of the type of provider, if an organization participates in Medicare, Medicaid, and related federal and state programs as sources of revenue, that revenue is at risk from third-party claims audits.

The AHA's RACTrac Survey for 2nd Quarter 2016[7] indicated that 40% of the medical records reviewed by Recovery Auditors had an improper payment, and 45% were appealed with a 60% success rate. While the appeal success rates are high for those that have the resources and tools to accurately manage the process in real time, there is still ultimately a significant impact to the bottom line for Medicare alone.

The healthcare industry invests a lot of time and money:

- Researching rejections/denials on a day-to-day basis, which may involve individuals from varying departments and levels within the organization:
  - Reduce A/R days by utilizing up-to-date regulatory and coding information to resolve rejections or denials quickly;
  - Educate on and/or modify processes to mitigate future risk; and
  - Minimize the rate of initial denials by effectively utilizing the discussion period.

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[4] CMS published figure in single updated report dated March 4, 2016 (National Program Total Corrections) at the following site https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Program-Reports.html

[5] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Program-Reports.html

[6] Fact Sheet: The Health Care Fraud and Abuse Control Program Protects Conusmers and Taxpayers by Combating Health Care Fraud, February 26, 2016, Department of Justice Office of Public Affairs.

[7] AHA RAC TRAC Survey, 2nd Quarter 2016, AHA.

[8] Data.medicare.gov, list of all Hospitals registered.

- Responding to audit requests:
  - Protect revenue by utilizing archived regulatory and coding information to validate and defend audit findings based on the applicable rules and regulations for the period in question.
- Participating in appeal efforts:
  - Utilize archived regulatory and coding information to demonstrate the rules and regulations for the period in question and minimize revenue impact; and
  - Maximize success rate on appeals by managing the process against the calendar to meet all deadlines with the right documentation.

Financial & Reputational Risk: Fraud & Abuse

Fraud & Abuse Risk

Utilizing data from the February 2014 HHS & DOJ Report calculating the government's ROI for enforcement at 800%,[9] divide the $4.34 billion in criminal and civil recoveries collected by the Medicaid Fraud Control Units by 4,780 total hospitals[10] to arrive at a figure of $908K average annualized risk per US hospital.

If an organization participates in Medicare, Medicaid, and related federal and state programs as sources of revenue, that revenue, not to mention the organization's reputation, is at risk from fraud and abuse. Reduce this risk by reducing the potential frequency of fraud and abuse incidents through an effective risk and compliance management program that:

- Surfaces areas of high potential exposures;
- Monitors and controls essential aspects of incidents, investigations, and remediation;
- Develops, communicates, and enforces policies and procedures to control activities within the organization; and
- Develops and maintains controls for contracts and relationships with professionals and independent organizations involved in providing services.

Financial, Operational & Reputational Risk: HIPAA

HIPAA Risk

Utilizing data from both the 2012[11] and 2013[12] Ponemon Insititute reports, including "[94%] of healthcare organizations in this study have had at least one data breach in the past two years... 45% report that they have had more than five incidents," and that HIPAA breaches average 28,723 records at a cost of $188 per breached record, an average cost of $5.4M per HIPAA breach can be derived or $2.7M average annualized risk per US hospital.

Regardless of what type of health care or health care services an organization provides, if they involve the utilization of Protected Health Information (PHI), and thus are a covered entity under HIPAA and HITECH, the organization will be at risk from a reputation-damaging and costly HIPAA breach, an OCR audit, an OIG audit, or all three. Reduce the potential frequency of breach incidents through an effective information security risk and compliance management program that:

- Surfaces areas of high potential risk exposures;
- Monitors and controls essential aspects of remediation, incidents, and investigations;

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[9] The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2012.

[10] Data.medicare.gov, list of all Hospitals registered.

[11] Third Annual Benchmark Study on Patient Privacy & Data Security, December 2012, Ponemon Institute.

[12] 2013 Cost of Data Breach Study: Global Analysis, May 2013, Ponemon Institute.

- Develops, communicates, and enforces policies and procedures to control activities within the organization; and
- Develops and maintains controls for contracts and relationships with professionals and independent organizations involved in providing services.

Financial, Operational & Reputational Risk: Meaningful Use

Meaningful Use Risk

Utilizing data in the November 2013 CMS report to Congress regarding the EHR Meaningful Use Incentive Program, divide the $10.9B paid to date by 4300 hospitals to calculate that the dollars at risk for Meaningful Use incentive payments are averaging $2.5 million per participating hospital.[13]

Any organization that attests to and accepts Meaningful Use Incentive payments will be at significant reputational, financial, and operational risk if discovered to be out of compliance. Do not be forced to pay back incentives and continue to qualify for next stage incentives—ensure continued participation in the incentive programs by:

- Ensuring the documentation of assessments and remediation projects performed for Meaningful Use attestation are continually kept up to date in a complete and readily available Book of Evidence; and
- Ensuring the results are indicating good and improving safeguards for PHI wherever it resides—both while in your possession and that of your Business Associates. (This is the goal indicated by the new provision in Appendix B to the 2014 OIG Work Plan regarding OIG's own planned audits.)

"In too many cases, compliance risk is calculated as a trade-off between the cost of compliance and the cost of the penalties the organization might incur. A cost-based analysis often makes sense from an operational viewpoint, where organizations place a premium on efficiency. But organizations that look at the broader impacts of compliance risk gain the advantage of better capitalizing on opportunities affecting their competitive posture and business objectives."[14]

—David Houlihan, Esq.

Financial & Operational Risk: Operational Inefficiency

Without centralized resources and standardized processes, an organization can waste a lot of time and effort on redundancies and inefficient processes. Reduce your risk by:

- Providing one consolidated location for accessing regulatory information and alerts to reduce time spent tracking information from various list serves, scouring websites, and multiple paid subscriptions to various publications;
- Reducing A/R days, including improving initial claim accuracy and reducing overall denial rates, by ensuring that staff have the needed regulatory information and tools to "get it right the first time"; and
- Centrally tracking operational modifications and activities needed to comply with regulatory changes, including your effort to incorporate regulatory changes into organizational processes in case of audit or investigation.

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[13]   November 2013 EHR Incentive Program Summary Report, CMS.

[14]   Compliance Risk and Business Strategy: Observations from the HIPAA Omnibus Rule, October 29, 2013, David Houlihan, Esq.

Conclusion

Health care organizations need to move way beyond a "paper program" to protect themselves from operational, financial, and reputational risk, not to mention the personal risk to their "Responsible Corporate Officers." Utilize technology that provides both control over and visibility into the organization's regulatory risk in order to move toward improved quality of care, or risk the organization's financial health by managing against unseen risk and chasing after compliance.

Solutions from Wolters Kluwer

Some 30,000 times a day, more than 1,000 organizations, including the OIG, CMS, FDA, and leading health law and consulting firms, turn to Wolters Kluwer Platform as a Service (PaaS) and Software as a Service (SaaS) solutions. Offering subscriptions at a fraction of the cost of additional staff, Wolters Kluwer products deliver the visibility and clarity needed to support regulatory and compliance decision-making from the board level down to the point of care, and the controls necessary to support a complete culture of compliance from the ground up.

ComplyTrack

www.complytrack.com

Your bottom line depends on it: the ability to manage risk and maintain an enterprise-wide culture of compliance in the face of constant change. ComplyTrack is a complete regulatory risk and compliance software solution, drawing upon Wolters Kluwer's unparalleled healthcare information and expertise. It provides the visibility, controls, and workflows required to support your enterprise-wide compliance and risk programs from the top-down and the bottom-up.

ComplyTrack workflow applications cover the entire enterprise:

- **Issue & Action Management:** Track and manage any issue or investigation completely and securely across the enterprise with the brand new Issue & Action Management application available on the redesigned ComplyTrack platform.

- **Incident Management:** Efficiently and effectively manage the entire life cycle of incidents with the flexible, customizable input, tracking, and reporting available in the Incident Management application on the redesigned ComplyTrack platform.

- **Risk Assessment Management:** Assess, interpret, communicate, and remediate risk across your entire enterprise in real time with the Risk Assessment Manager.

- **Survey Management:** Capture and manage evidence of compliance with Survey Manager, a sophisticated, comprehensive, and customizable tool that puts you securely in control.

- **Information Security Assessment Management:** Effectively manage the growing regulatory burden of information security and privacy with the workflow, controls, and reporting built into the Information Security Assessment Manager.

- **Documents & Policy Management:** Create, manage, and distribute documentation while maintaining strict control across the enterprise with the Document Policy Manager.

- **Contracts & Vendor Management:** Effectively monitor and manage all your contractual and arm's-length relationships across the enterprise with the Contract & Relationship Manager.

- **Audit Management:** Proactively manage all facets of your claims-based audit process from first letter to final appeal using the Audit Detail Manager.

Coding Suite
www.mediregs.com/coding-suite

Maintain control over your bottom line in the face of regulatory change: ensure accurate, timely reimbursement through accurate and efficient coding. Coding Suite provides advanced primary source content and expert tools — updated in real time — to ensure the integrity of your program, revenue, and audit documentation. Available in three levels, Coding Suite includes all the resources that your coding, billing, reimbursement, and HIM team needs to work effectively, whether it is a simple coding tool with integrated medical necessity information, support for claims processing rules and edits, a provider-specific Medicare-compliant reimbursement resource, or critical audit analysis tools.

Compliance Suite
www.mediregs.com/compliance-suite

Quickly access the up-to-date information you need to make informed compliance and reimbursement decisions while streamlining workflow processes. Compliance Suite brings you the immediate access to advanced, up-to-date primary source content, and expert tools you need to ensure ongoing program and revenue integrity as well as proper audit documentation. Available in three levels, Compliance Suite is configured to provide the resources each member of your compliance, reimbursement, and risk team needs to work efficiently, whether they need to conduct quick, high-level CFR and FR searches, take a deeper dive to support compliance program reviews and accreditations, or have access to an all-inclusive research portal complete with coding tools and resources. ■