2018 Healthcare Compliance Benchmark Report

SAI GLOBAL

STRATEGIC MANAGEMENT SERVICES

Contents

Executive Summary ———————————

For the past 20 years, an increasing number of healthcare organizations have focused on the development and implementation of compliance programs. However, evidence suggests that many of these programs are not fully developed or effective. One of the purposes of the Healthcare Compliance Benchmark Survey is to gain better understanding of the status and progress of compliance program development in the healthcare sector.

This report represents SAI Global's ninth annual survey gathering data and developing insights from compliance professionals in the healthcare provider industry. This year the survey was a collaborative effort with Strategic Management Services, LLC, nationally recognized experts in compliance consulting services for the healthcare industry. Respondents to the survey were asked questions relating to the seven elements of an effective compliance program, along with information regarding demographics, resource levels, reporting relationships, operation of the compliance program, and compliance priorities for the coming year. There were 388 survey respondents from provider organizations representing nearly every state ranging from very small entities to large healthcare systems. This report examines and includes detailed findings, and will shed light on strategies to make compliance programs more effective.

Healthcare Compliance Trends

Highlights of Nine-Year Trends ————————————————————

Budget Expectations
Results from 2018 are consistent with past years in that 50% of respondents expect their budgets to remain essentially the same, 25% expect increases, 10% are looking for reductions, and the balance are unsure. (see page 8)

Compliance Office Operations Priorities
Evidencing program effectiveness remained the top priority for 2018, as it was for 2017. Compliance training remained one of the top three priorities again this year, as it has been for the last eight of nine years of the survey. However, improving compliance auditing ranked as the number-two priority this year. Policy and investigative management remained high priorities for about one-third of respondents. (see page 15)
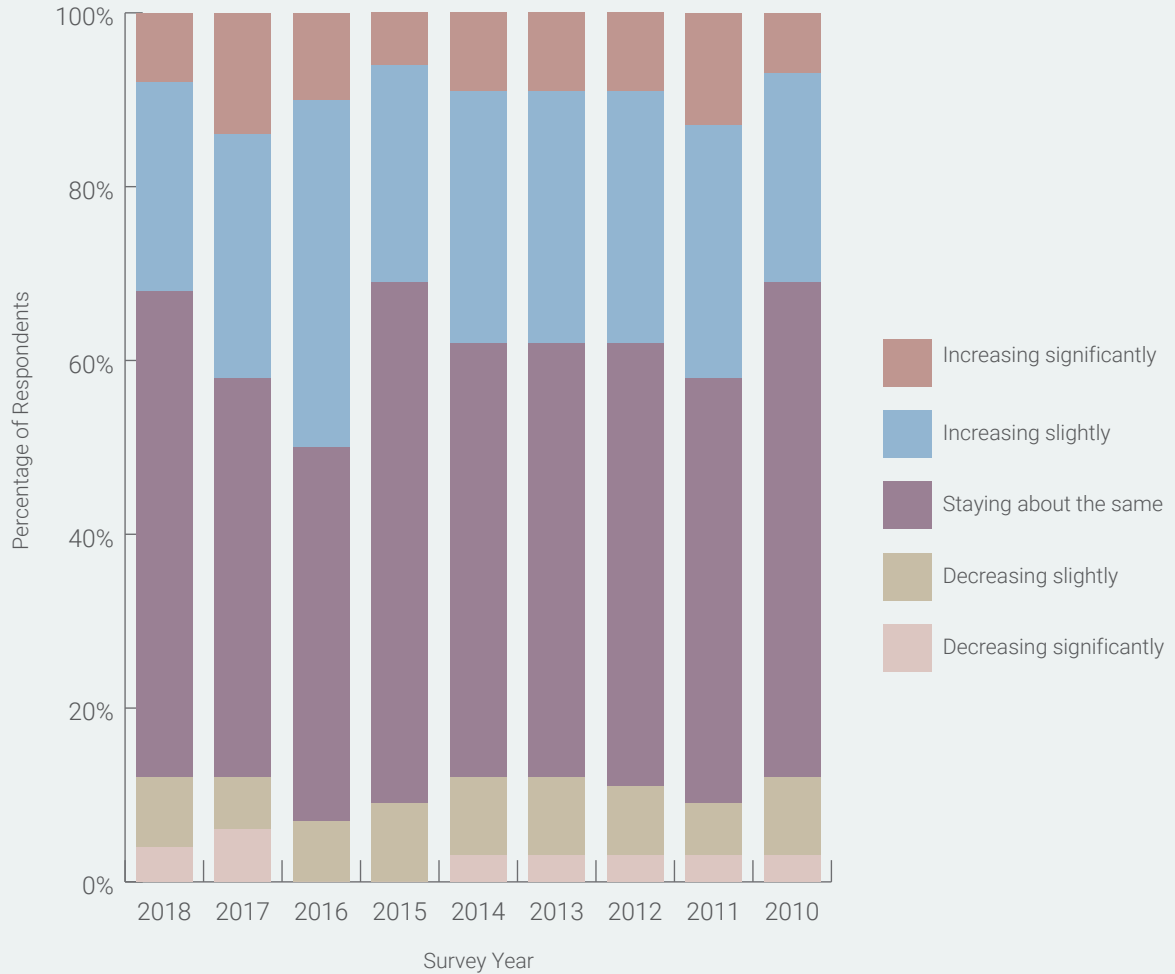
Compliance High Priorities
Similar to last year, arrangements ranked fifth in priority (35%), and claims accuracy (44%) was in third place. However, the biggest change related to HIPAA security/cybersecurity, which moved into first place in terms of high priority (64%), and HIPAA Privacy, which followed in second place (51%). The recent high-profile cases (see page 24) involving data breaches of protected health information, much of which resulted from cyberattacks, likely influenced this change. Troubling, though, is the fact that the number-one regulatory and enforcement priority of the Office of Inspector General (OIG) and Department of Justice (DOJ) remains corrupt arrangements with referral sources, and in second place for them is the issue of false claims. Together, they constitute virtually all the major enforcement actions and penalties and represent a far greater exposure to liabilities than security breaches.

Methods for Demonstrating Program Effectiveness
As in prior surveys, respondents continue to rely upon process measurements such as using checklists and tools (65%) and internally generated and administered surveys (33%) that result in subjective analysis. These are great tools for monitoring the program but do not meet the standard of an independent evaluation focused on measuring outcome. Only 25% have their compliance programs independently measured for effectiveness, relying instead on self-assessments, checklist tools, internally generated surveys, and the like. (see page 26)

Nine-Year Trend: Compliance Program Budget

Percentage of Respondents

Survey Year

- Increasing significantly
- Increasing slightly
- Staying about the same
- Decreasing slightly
- Decreasing significantly

SEVEN STANDARD ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

Designation of Compliance Roles

Monitoring Of Programs with High Compliance Risks

Disciplinary Action and Employee Screening Guidance

Compliance Education and Training

Investigation, Resolution, and Reporting

Effective Employee Communication

Written Compliance Guidance

Source: Office of Inspector General (OIG), Health and Human Services (HHS)

Overview and Objectives

As organizations implement compliance programs, it has become very clear that just ensuring that the seven standard elements of a model compliance program are in place is not enough. The process of adding these elements does not ensure that they are effective in meeting compliance objectives. It is clear that organizations must also put in place processes that systematically measure the effectiveness of programs on a regular basis. The message from the OIG and the Department of Justice is very clear: having an effective compliance program can be a mitigating factor when assessing culpability, potentially resulting in reduced penalties and/or more favorable settlement terms.

Seven Standard Elements of an Effective Compliance Program

1. Written compliance guidance (Code of Conduct, Compliance-Related Policies)

2. Designation of compliance officer and Compliance Oversight Committees

3. Effective compliance education and training

4. Effective lines of communication with employees (e.g. hotline)

5. Guidance regarding disciplinary action; new employee screening

6. Ongoing monitoring and auditing of programs with high compliance risks

7. Prompt investigation, resolution, and reporting of potential violations

The SAI Global and Strategic Management Service's 2018 Healthcare Compliance Benchmark Survey was designed to assist compliance officers in understanding where their compliance programs stand in relation to the industry at large. It is the intention to provide results of the survey in a way that will shed additional light on what organizations are doing or not doing with regard to their compliance programs. The results from the survey and the comments associated with it are based upon responses received from representatives from 388 different healthcare organizations, including hospitals, home health agencies, physician practices, and skilled nursing facilities, among others.

> Respondents clearly evidenced considerable energy in implementing effective compliance programs

People and Personnel

Staff Level of Compliance Offices

How to Get By with a Skeleton Crew

OIG compliance guidance states that the compliance officer "should have sufficient funding and staff to perform his or her responsibilities fully" and then enumerates a long list of responsibilities. The survey collected data with respect to the adequacy of resources for compliance officers in meeting this challenge. An interesting result was the fact that one-third of respondents indicated that their organizations have only one person in the compliance office. Of that number, 20% stated it is one full-time person in the office, with **13% stating it is only a one-person, part-time job.** Forty percent of respondents stated their offices have between two and five persons, and the remaining quarter reported having over six people.

OBSERVATIONS: The OIG notes in its compliance guidance that for the compliance program to be found effective, it must be adequately staffed and have budgetary resources to enable it to meet its objectives. Over the years, the roles and responsibilities have been evolving beyond the original compliance guidance by the OIG. As is noted elsewhere in the survey, most compliance offices have had other responsibilities added, particularly HIPAA Privacy and internal audit. Responses to this question of the survey suggest that many compliance offices are operating with less than fully adequate resources to meet their obligations.
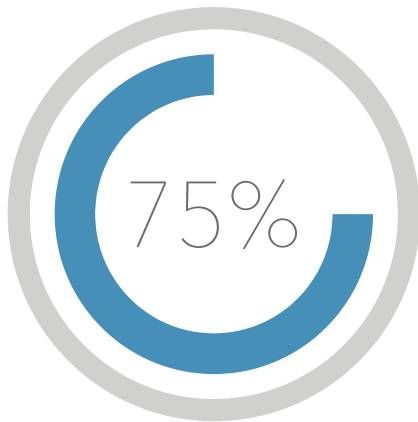
75% have 5 or fewer staff members
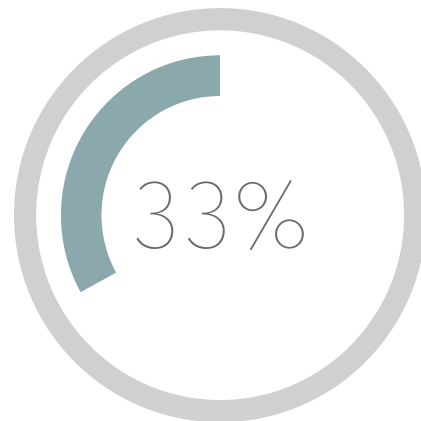
33% operate with one part-time or full-time person

Resource Levels Anticipated In 2018

More Work, Same Budget

The survey collected data around what compliance officers are looking forward to in 2018 with respect to their budgets. Results from 2018 are consistent with past years in that 50% of respondents expect their budgets to remain essentially the same, 25% expect increases, **10% expect *reductions***, and the balance are unsure.

OBSERVATIONS: Adequate resources are required to accomplish a mission, and this includes budget. The increase in responsibilities during a time of heightened enforcement by government agencies is, in all likelihood, stretching resources for most compliance offices. As noted elsewhere in the survey results, many engage vendors to provide services more efficiently and at a lower cost than would be the case with specialized in-house staffing.

28%
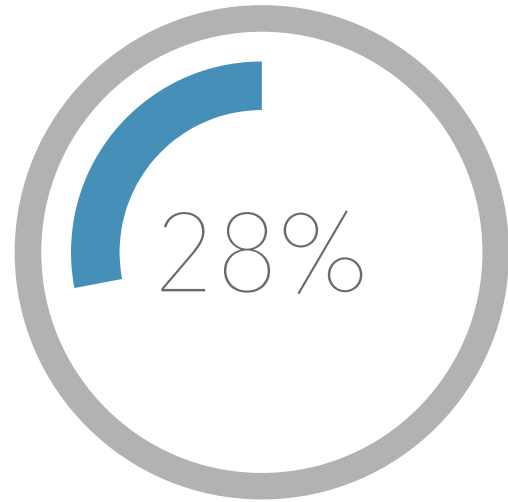
Only 28% expect increases in their budgets for 2018

To Whom Compliance Reports

Who's The Boss?

Nearly half of the survey respondents stated that they report to the CEO. However, some organizations are using others to oversee the program. Fifteen percent of respondents indicated their compliance officer reports to legal counsel. The balance of the respondents provided answers that included a wide variety of other people, including the CFO.

OBSERVATIONS: The OIG compliance guidance and U.S. Sentencing Commission guidelines call for the compliance officer to report directly to the CEO. The fact that half of respondents indicated the compliance officer reporting to someone other than the CEO brings into question whether the programs are meeting expectations of oversight agencies.

Both the OIG and DOJ oppose the notion of reporting to legal counsel, as they view attorneys as advocates for the organization and not independent gatherers of fact and evidence who would voluntarily disclose violations of law and regulation to appropriate authorities. They have also found in many cases that legal counsel will attempt to designate information that should be disclosed as privileged information. Yet, despite very public concerns about such reporting relationships, 15% reported that is the case in their organization. In some other cases, the reporting relationship is through the CFO, and that also is considered by regulatory agencies to be a poor practice and a conflict of interest, in that much of the work of the compliance officer is to review the revenue cycle and other financial issues falling under the CFO.

Only half of compliance officers report to the CEO	**50%**
And 15% of compliance officers report to legal counsel	**15%**

Compliance Program Oversight by Executive Leadership

Teamwork Makes the Dream Work

Survey results showed that 85% indicated that their organizations have an Executive Compliance Committee whose function is to provide executive oversight. The makeup of the committee for most organizations includes key executives, and 87% have the CEO as part of the committee. Most organizations also include on their compliance committee the COO and CFO. About half of the respondents indicated that legal counsel and human resources are on the committee as well. Revenue cycle, risk management, internal audit, information technology, and quality assurance personnel, as well as program managers, were also prominently listed as members of committees for many organizations.

OBSERVATIONS The OIG and DOJ have made it clear that top leadership has responsibilities for support of the compliance program, and when organizations fail to evidence them, these organizations face potential adverse actions by the government. It is important, therefore, to establish a management compliance committee to advise the compliance officer and assist in the implementation of the compliance program. Furthermore, the OIG has its Accountable Executive Doctrine and the DOJ has the Yates Memorandum, both of which focus on executive accountability for wrongdoing as a result of negligence of their responsibilities for compliance. **One way for executives to evidence they are not negligent with regard to compliance programs is by active involvement in an oversight committee**. Having noted this, it is understandable that some organizations, such as individual physician practices, may not lend themselves to having such a committee because of size and organization.

85% of survey respondents have executive leadership compliance oversight committees
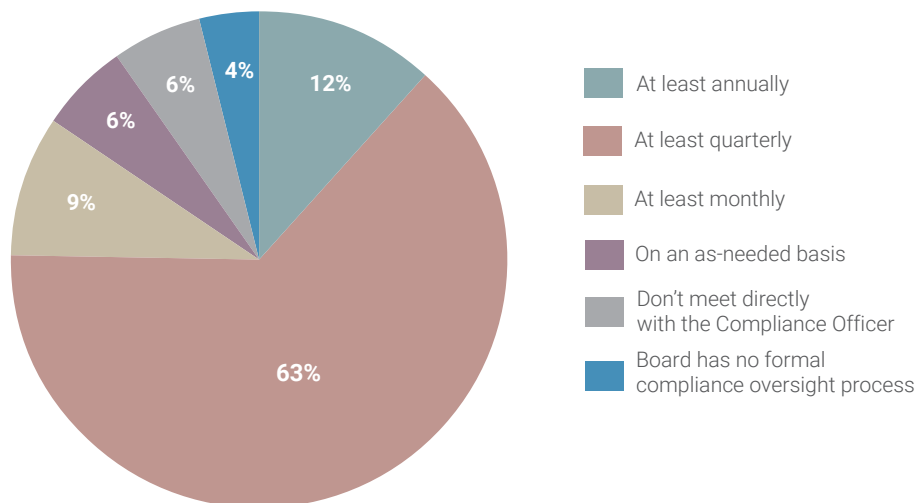
Board Oversight of Compliance

Get the right people on the bus and in the right seat

The OIG clearly states that effective compliance programs begin at the top and cascade down through the executive ranks and compliance office to all covered parties. Nearly two-thirds of respondents indicated that the compliance officer meets with the board at least quarterly, which is considered a best practice. All other respondents fall short of that practice. Twelve percent of survey respondents indicated that it is an annual appearance, with 9% meeting at least monthly and 12% reporting meeting as needed or not at all. About 3% reported no formal oversight board.
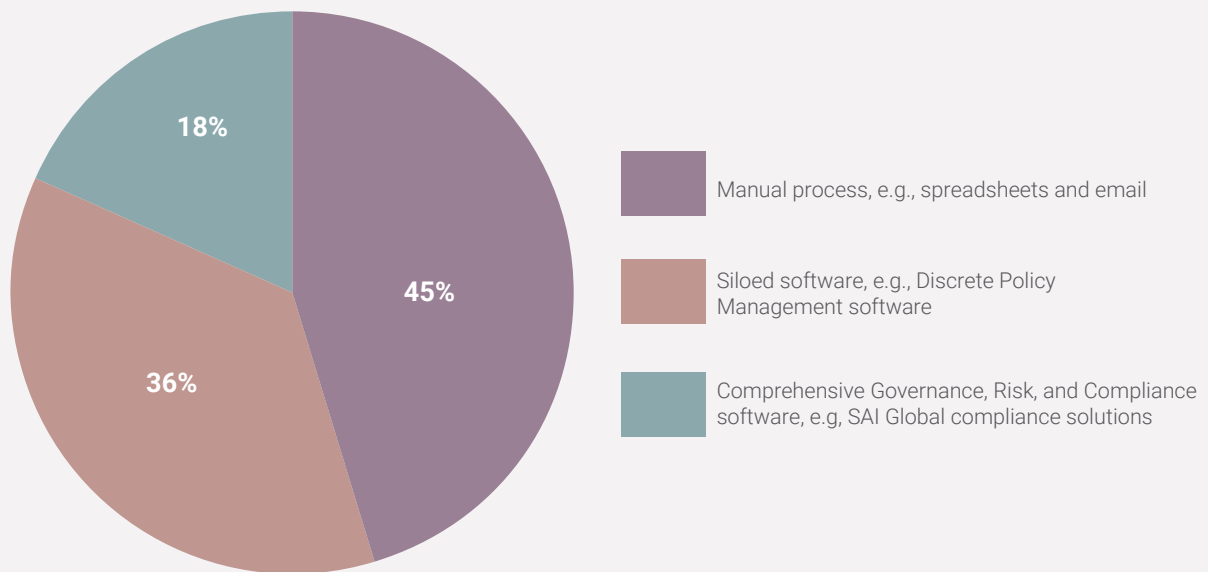
OBSERVATIONS The OIG has increasingly added provisions to its Corporate Integrity Agreements (CIAs) that mandate board attestations/certifications that fiduciary obligations for overseeing compliance programs are being met and in some cases require the engagement of compliance experts to assist organizations in meeting their obligations. The majority of survey respondents meet the best practice standard. Unfortunately, meeting monthly is not a positive response, in that it leads to too much interaction with something that is primarily a management function. **The worst response was the 15% that meet as needed or not all or have no formal oversight.**

How often does the Compliance Officer meet with the Board or Board Compliance Committee?

Legend:
- At least annually
- At least quarterly
- At least monthly
- On an as-needed basis
- Don't meet directly with the Compliance Officer
- Board has no formal compliance oversight process

Pie chart values: 12%, 63%, 9%, 6%, 6%, 4%

Methods and Procedures

What type of technology do you use to facilitate document management at your organization?

- 45% — Manual process, e.g., spreadsheets and email
- 36% — Siloed software, e.g., Discrete Policy Management software
- 18% — Comprehensive Governance, Risk, and Compliance software, e.g, SAI Global compliance solutions

Compliance Document Management

*Are You Managing Your Documents, Or Are Your Documents Managing You?*

The HHS OIG describes compliance-related documents in the following way:

> "At a minimum, comprehensive compliance programs should include … the development and distribution of written standards of conduct, as well as written policies and procedures that promote the [organization's] commitment to compliance and that address specific areas of potential fraud, such as claims development and submission processes, code gaming, and financial relationships with physicians and other healthcare professionals."

The U.S. Sentencing Commission notes, "have an effective compliance and ethics program … [A]n organization shall … establish standards and procedures to prevent and detect criminal conduct." The best practice is to review the organization's internal ethics and compliance code and compliance-related policies annually to ensure they are up-to-date and compliant with current regulations and standards. **Only six out of ten respondents indicated following that practice. The balance that do not are running risks of liabilities.**

Controlling and managing compliance-related policies and procedures are among the most challenging areas for compliance officers. The failure to keep track of rescinded or revised policies is another common problem with potential liability consequences. Roughly half of the survey respondents reported that they manage the process manually, with one-third using document management software and one-fifth using a comprehensive document management system.

50% — Half manage compliance documents manually

50% — Half use document management software or systems
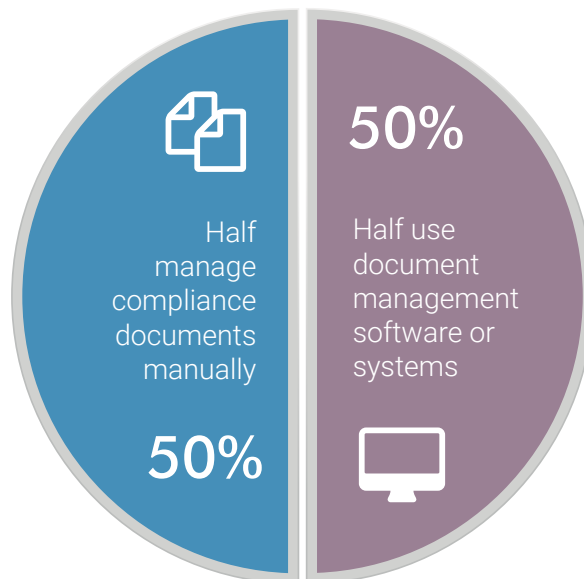
OBSERVATIONS: Development of compliance policies in an *ad hoc* manner and lack of policy tracking can result in overlapping or duplicate policies, potentially creating significant liability. Managing compliance-related policies manually with hard copies in a binder or through spreadsheet software is not advisable, as such practices can invite problems and potential liability. It is far more efficient and economical to find tools that can assist in policy management. An organization can protect its people and reputation only by ensuring a formal policy management process is in place to create, distribute, and update necessary policies and procedures.

Compliance Office Work Plans

Plan the Work; Work the Plan

The survey probed how compliance officers develop their annual work plans to meet their responsibilities for ensuring all high-risk areas are operating in compliance with applicable laws, regulations, and organizational codes of conduct and policies. Program managers should engage in ongoing monitoring of their areas of responsibilities. Respondents evidenced drawing upon a variety of resources in developing their work plans for the year, with three-quarters or more drawing upon the OIG Work Plan, Compliance Risk Assessments, and Reported Compliance Investigations in deciding on their 2018 work. A majority also identified prior audits/review and government audits as being useful. Many also identified other regulatory agency information as resources. Only 6% indicated they have no work plan.

OBSERVATIONS: The compliance work plan should focus on ongoing auditing of programs with compliance high-risk areas to verify program managers are addressing issues within their areas of responsibility, as well as to validate that the compliance controls are effective in achieving desired outcomes. This does not mean that the compliance officers are expected to do all the auditing. They can assist in coordinating internal compliance review and monitoring activities. This can be done in a variety of ways, incorporating as necessary internal audit, outside consultants, and program managers, independent of the areas being reviewed. **Compliance officers have to carefully assess the best use of limited resources in meeting their obligations.**

Only 6% do not have compliance work plans

Compliance Education And Training

"Tell Me And I Forget. Teach Me and I Remember."

70%
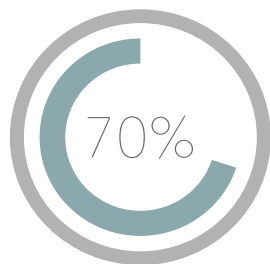
70% train at new employee orientation and annually thereafter

Two-thirds use learning management systems; only one in five deliver live training

Development and implementation of regular, effective education and training programs is one of the seven critical elements of a compliance program. Most respondents reported that their organizations provide compliance training at the time of new employee orientation and annually thereafter, which is considered a best practice. The remainder reported training annually or during orientation. Nearly half of respondents reported that compliance officers are responsible for tracking completion of compliance training, with most of the others reporting this as an HR responsibility.

It is generally recognized that the most effective training is delivered using live trainers and facilitators. However, live training is also the most expensive and time-consuming method. Two-thirds of respondents indicated their organizations use learning management systems to deliver training, while twenty percent use live trainers.

OBSERVATIONS: The OIG states:
"At a minimum, comprehensive compliance programs should include … the development and implementation of regular, effective education and training programs for all affected employees … The compliance officer's primary responsibilities should include … developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program and seeks to ensure that all appropriate employees and management are knowledgeable of, and comply with, pertinent Federal and State standards" It further advises that all affected parties "should be periodically trained in new compliance policies and procedures."

A key question is **how effective the training program is in delivering the messages**. This has nothing to do with how many people have been trained, but how much they learned from the training. **Using measurement tools to determine training effectiveness is critical.** Tests, surveys, and interviews during compliance program evaluations can provide credible evidence as to the effectiveness of the training and the degree to which employees recall and adopt the principles included in the lessons.

Compliance Communication Channels

Caller, Are You There?

Employees should have direct access to the compliance officer; virtually all of respondents stated that is the case in their organizations. However, their compliance guidance documents call for multiple compliance communication channels, with hotlines – by far – the most important for effective compliance programs. Employees differ on their preferred method of reporting compliance concerns, but the **best practice is more than one channel, including offering both a live operator hotline and web-based reporting.** Virtually all healthcare entities maintain a hotline for reporting wrongdoing and channeling employee concerns, allegations, and complaints. Failure to offer, encourage use of, or act upon information provided by this compliance channel of communication creates a serious risk of increased exposure to liabilities.

OBSERVATIONS: The OIG, Sentencing Commission, DOJ, and other authorities call for hotlines to:

- ⮑ permit employees to report anonymously;
- ⮑ offer confidentiality for those that identify themselves; and
- ⮑ warrant no retaliation or reprisals for reporting potential violations of law, regulations, codes, or policies.

The most widely-accepted compliance communication channel is a hotline available 24/7 to take complaints, concerns, and allegations of wrongdoing. If employees cannot or do not feel comfortable reporting internally, they can do so outside the organization**. An internally operated hotline is rarely effective, and voice mail hotlines are sub-optimal;** neither assures anonymity

or permits debriefing of complainants unless they formally identify themselves. Using a professional hotline vendor is an all-around best practice. Email reporting is fine, except it is too public and not secure. It also doesn't provide opportunity for anonymity or confidentiality.

60% use a hotline vendor
55% use internal hotlines
38% use voice mail reporting
2% have no reporting channel
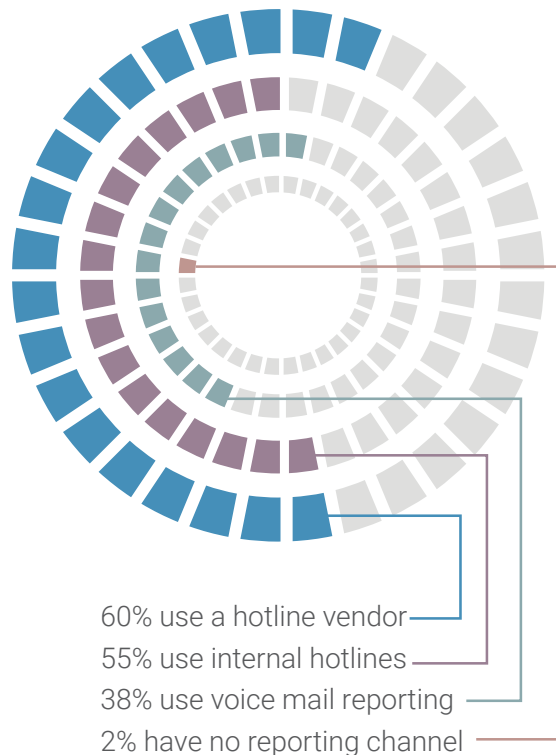
Tools and Services Employed by the Compliance Office

It Takes a Village

Most respondents reported using tools and services provided by vendors. Co-sourcing for routine services is increasingly common in healthcare compliance, permitting the compliance office to focus on core responsibilities. According to survey results:

- ◗ eight out of ten use a hotline service;
- ◗ two-thirds use vendor sanction screening and e-learning tools;
- ◗ nearly half use document management and policy/code development tools; and
- ◗ one-third use vendor compliance survey tools.

OBSERVATIONS: The reliance upon vendor tools is a major industry movement that transcends compliance. Most organizations look for ways to use vendors to assume duties that support, but are not part of, the core business. In most cases, vendors can provide better expertise in certain areas and are significantly less costly and more efficient than using in-house staff to do the work. This preserves employees to work on the core work.

Most rely upon vendors for hotline services, e-learning programs, sanction screening, and document management tools

Program Operations

Compliance As An Element Of Performance Evaluation

The Yardstick for Performance Evaluations

OIG compliance guidance states that compliance programs should require that the promotion of, and adherence to, the elements of the compliance program be a factor in evaluating the performance of managers and supervisors. In the survey, the respondents split nearly down the middle, with **half indicating they have such provisions.**

OBSERVATIONS: Despite clearly stated rules to aid in the performance review of a role, half of organizations do not meet this standard. The OIG goes further on this subject by calling for managers, along with other employees, to be trained in new compliance policies and procedures and be held accountable for following that written guidance in their performance evaluations. The OIG also states that there should also be a policy stating that managers and supervisors will be sanctioned for failure to adequately instruct their subordinates or for failing to detect noncompliance with applicable policies and legal requirements.
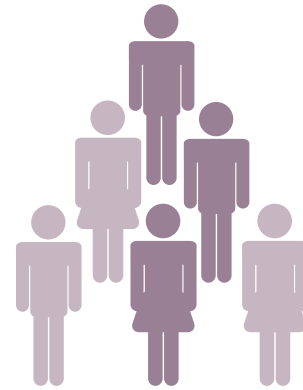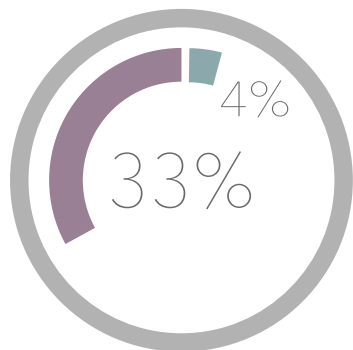
Half do not have compliance adherence as an element in performance plans

# Using Surveys to Evidence Compliance Program Effectiveness

Survey Says: Get Audited Independently

4%
33%

33% use surveys, but only 4% use one that is professionally developed and independently administered

Survey results indicate about 60% have not used surveys as a means of measuring compliance program effectiveness. Most that have used them have mainly relied upon internally developed and administered ones (33%), **with only 4% using professionally developed ones, administered independently.** Internally developed and administered surveys may be questioned by employees and those reviewing results as being biased or unreliable. For the most credible and useful results, it is far better to use a valid and independently administered survey that has been tested over many organizations and is administered through a web-based system that ensures confidentiality of participants.

OBSERVATIONS: Survey of employees is one of the methods advocated by the OIG in its Compliance Program Guidance. It notes that "as part of the review process, the compliance officer or reviewers should consider techniques such as … using questionnaires developed to solicit impressions of a broad cross-section of the hospital's employees and staff." The OIG further reinforces this by stating that it "recommends that organizations should evaluate all elements of a compliance program through 'employee surveys'." Results from a professionally administered survey can provide a very powerful report to the compliance oversight committees, as well as to any outside authority questioning the program. They can also identify relative strengths in the compliance programs, as well as those areas requiring special attention. There are two general types of surveys that can be employed to evidence compliance program effectiveness: compliance culture surveys and compliance knowledge surveys. However, respondents clearly favor developing and administering surveys internally. This is not a best practice.
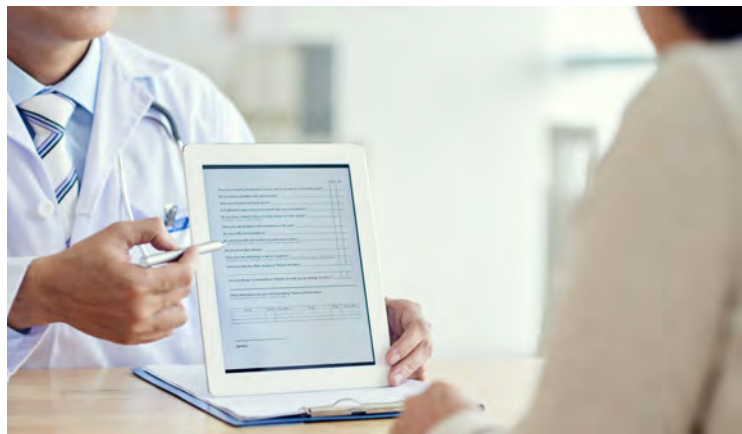
Increased Responsibilities for the Compliance Office

Same Title, More Work, More Responsibility

One of the trends observed in the healthcare sector is the tendency to have the compliance officer assume additional responsibilities, placing additional stress on the function. In many cases, this is not accompanied by added resources, resulting in a strain on the compliance officer office (see key insight 1).

Broken down:

- 75% reported the compliance office having responsibility for HIPAA Privacy
- Nearly a third indicated responsibility for HIPAA Security
- Nearly half of respondents indicated responsibility for internal audit
- 37% had responsibility for risk management
- 24% indicated the same for quality

One of the interesting results was that 15% stated that they are responsible for legal counsel. Unfortunately, both the DOJ and the HHS OIG have trouble accepting this. They view legal counsel as representing the organization, and its leadership as an advocate. In many cases they have encountered situations in which legal counsel has tried to designate information as privileged to avoid disclosure to the government.

OBSERVATIONS: For many organizations, the compliance officer is a convenient party to assume a variety of other duties as organizations tighten their budgetary belts. Care should be taken in assuming new duties beyond the traditional compliance ones, especially where it risks undermining the compliance program.

The areas that should not be part of compliance include risk management that clearly goes beyond the boundaries of corporate compliance. In many cases, these areas involve clinical issues outside the expertise of the compliance office. **The worst situation is one in which legal counsel is placed under the compliance office.** This clearly runs afoul of OIG- and DOJ-stated positions.
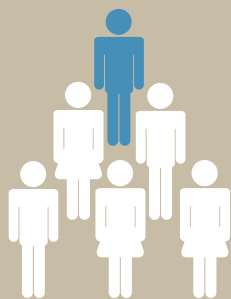
Most responsible for HIPAA Privacy & Internal Audit; one out of six responsible for legal

Sanction Screening

Making a (Sanction) List and Checking It Twice (or More)

60%

60% of respondents follow a best practice of screening at the time of engagement and monthly thereafter

Two-thirds use a vendor tool or service to facilitate sanction screening, with one-third doing it manually

The survey questioned the sanction screening process in terms of what databases are checked, frequency of screening, and who is primarily responsible for the managing the process. Survey respondents use the key sanction databases that have been identified by regulatory and enforcement agencies. The OIG List of Excluded Individuals and Entities (LEIE) was reported as being checked by 95% of respondents, followed by three-quarters who reported screening against the GSA Debarment Listing. Seven out of ten reported screening against the state Medicaid sanction databases. One-third reported screening against the Office of Foreign Asset Control (OFAC) list. The Drug Enforcement Agency (DEA) maintains a list of prescribing physicians and pharmacists sanctioned by them for criminal actions

involving Category I and II controlled (narcotic) drugs, and one-third of respondents screen against this listing. One-fourth of respondents screen against the Food and Drug Administration (FDA) sanction database that contains actions taken against clinical investigators participating in studies involving investigational new drugs, antibiotics, biologics, medical devices, medical foods, or food additives that violated their authorities. One out of ten respondents reported extending sanction screening to other agencies' databases as well.

In terms of frequency of sanction screening, most follow the best practice standard of screening at the time of engagement and monthly thereafter. **A minority of respondents answered that they screen prior to engagement only (9%), screen only annually (3%), or, worst of all, do not sanction screen at all (5%).**

Two-thirds of respondents reported using a vendor to assist with sanction screening by either utilizing their search engine tool (23%) or outsourcing the whole function to the vendor (41%). This left nearly a third that use staff to check each database manually and resolve potential "hits," a very labor-intensive process.

It was clear that most organizations divide the responsibility of sanction screening in some way. Nearly two-thirds identified HR with sanction screening responsibility, with 60% identifying the compliance office as being responsible; about one-third identified credentialing as responsible, 21% cited procurement being responsible, and the remainder of about one in ten indicated other parties.

All but 5% sanction screen against the LEIE, with 76% and 70% screening against the GSA Debarment and Medicaid lists.

For most, sanction screening is a shared responsibility according to the type of party being engaged.

OBSERVATIONS

Sanction screening against the OIG List of Excluded Individuals and Entities (LEIE) is a must for compliance programs. It is mandatory as it relates to CMS Conditions of Participation. The OIG will take action and impose penalties on providers using sanctioned parties, as they consider any claims that include a sanctioned party to be potentially false and fraudulent.

There are many sanction databases in addition to the OIG LEIE and GSA EPLS, such as Medicaid sanction databases in 40 states, FDA, DEA, etc.

Several different parties, such as compliance, HRM, and procurement, may share responsibility for sanction screening to address different categories of parties (employees, vendors, contractors, etc.)

High-Risk Areas And Priorities

Risky Business!

One of the most revealing sets of issues related to priorities of compliance for 2018. A continuing major challenge for compliance officers is how to address ongoing monitoring and ongoing auditing of high-risk areas. The highest priority for most compliance offices related to HIPAA Privacy and Security.

Half of respondents identified HIPAA Privacy as a high priority. Further, 64% said the same for HIPAA security/cybersecurity. The next highest two areas cited were claims accuracy (44%) and government audits (41%). These are areas that the DOJ and OIG have placed as their top two priorities in healthcare enforcement. **Arrangements with referral sources continue to be a high priority for only about one-third of respondents. This is surprising, given that the DOJ and OIG have repeatedly declared this as their number-one enforcement priority.** The DOJ reported that 93% of its civil fraud cases came from whistleblowers alleging violations of the Anti-Kickback Statute and Stark laws, and the overwhelming majority of Corporate Integrity Agreements with the OIG have as their foundation violations of those laws.

OBSERVATIONS: It is interesting as to why, in the face of the priorities of the enforcement agencies, those compliance officers are not placing these as higher-risk area priorities. It may be advisable to consider realigning priorities to be more in line with those set out by the regulatory and enforcement agencies. Part of the reason arrangements with referral sources are pushed back by many is the concern about having conflicts with legal counsel. Virtually all arrangements have been prepared by attorneys, with many objecting to compliance officers reviewing what they have done; however, it is noteworthy that virtually all Anti-Kickback and Stark law enforcement actions deal with arrangements that involved legal counsel. As such, this is an area that warrants review and auditing. The key point is that the arrangement contract is only one small piece of the whole picture examined by government authorities. Once again, it is a matter of having these areas reviewed, but not necessarily by the compliance officer. Often, the answer is having outside experts assist in such reviews.

The top compliance high-risk areas cited by the DOJ and OIG don't coincide with respondent priorities

HIPAA Compliance Readiness

Sleepless Nights Worldwide, Brought to You By Cyberattacks and Data Breaches ———

Overwhelmingly, data breaches were the highest-ranked priority among the survey respondents. Two-thirds of respondents cited HIPAA security/cybersecurity, and over half cited HIPAA privacy as their number-one concern. Surprisingly, about 20% of respondents this year indicated high confidence in their preparation for an OCR audit, whereas last year that number was at 30%. **However, 60% indicated moderate confidence in their readiness this year,** versus about 50% in 2017. The "not very confident" and "does not apply" were about the same as in prior surveys.

Two-thirds of respondents indicated strong or full confidence in their controls for preventing PHI data breaches. Another 30% indicated only limited confidence in their controls.

## HIPAA Privacy/Security rated as highest priority for 2018 breaches

OBSERVATIONS: Clearly, this is an area that has drawn in compliance officers after so many cases of cyberattacks and data breaches flooded the healthcare sector. Also, the high activity level of the OCR in investigating and taking action on security breaches of protected health information, along with their increased level of auditing providers, is reflected in the movement toward placing greater priority on addressing HIPAA compliance.

How prepared is your organization for a HIPAA compliance audit from OCR?

- 18% Highly confident
- 61% Moderately confident
- 17% Not very confident
- 4% N/A or don't know
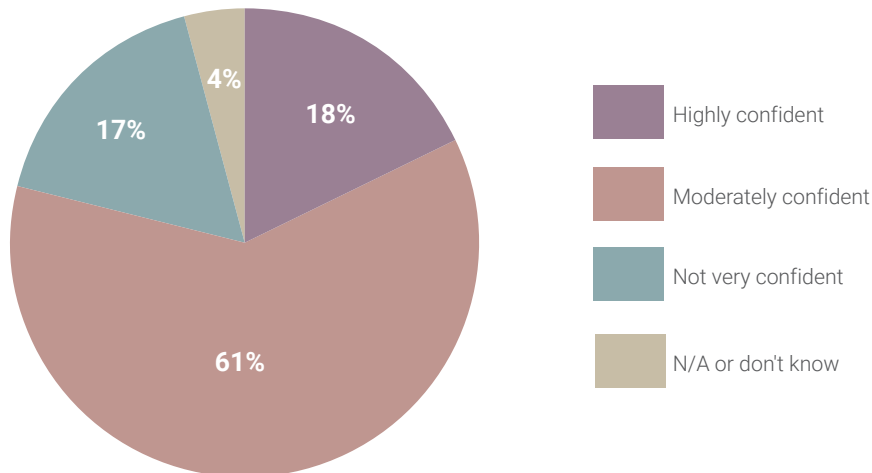
Evidencing Compliance Program Effectiveness

Keeping an Arm's Length Away from Measuring Your Own Effectiveness
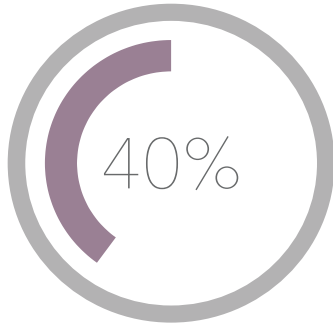
40% have never had independent compliance program evaluation

Two-thirds use self-assessment tools and checklists to evaluate program effectiveness

Most organizations do not have independent evaluations of the compliance program, relying instead upon self-assessment tools and checklists, internally generated surveys, and after-training testing. Only 25% of survey respondents use outside experts to evaluate their programs, and only 4% use validated and independently administered surveys. These are the two most credible means of evidencing program effectiveness. **Most telling is that 15% do not have any evaluation of their programs.**

OBSERVATIONS: Having independent compliance effectiveness evaluations is growing in importance and has been reinforced repeatedly by the OIG in its practical guidance. It has gone so far as to urge boards to engage compliance experts to assist them in providing active oversight of the compliance program. The OIG Corporate Integrity Agreements (CIAs) now mandate boards engage compliance experts to advise them on the program and then have them personally certify its effectiveness. Approximately 60% of survey respondents indicated they had a program evaluation at some point. However, most do not use independent outside parties to review, audit, and evaluate program

effectiveness, instead relying upon self-assessment checklists. This would be viewed as ongoing monitoring, not ongoing independent auditing of the program.
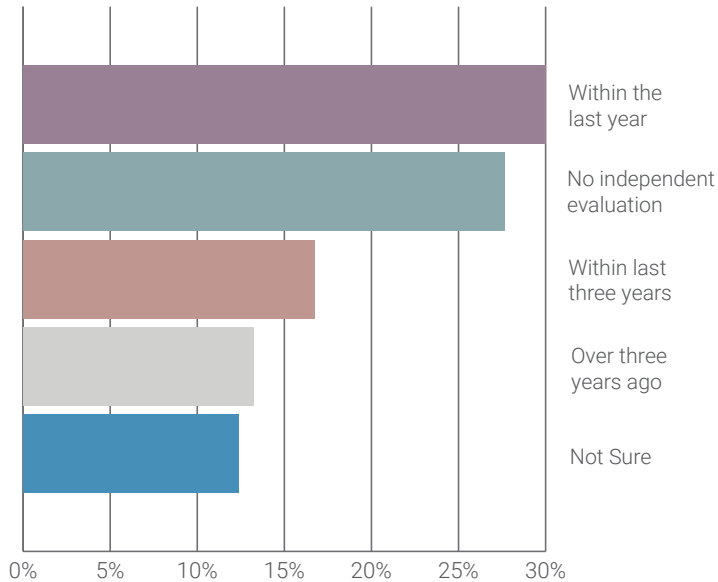
The OIG compliance guidance calls for all compliance programs to undergo independent effectiveness review and auditing. **Effectiveness relates to outcome of process, not the process itself.** That is to say, not doing an action means a failure to meet this standard. Compliance officers, like all program managers, are responsible for ongoing monitoring of their programs, but cannot audit their effectiveness. To be at all credible, that must be done by parties independent of the program.

Using checklists can be useful for ongoing monitoring. But internally generated compliance surveys lack credibility. Outside parties (board level, government oversight agencies) don't place much value on them. Most employees don't trust them, especially in ensuring anonymity in responses. Furthermore, it is difficult to know what the scores truly indicate.

Survey results suggest many confuse ongoing monitoring and ongoing auditing as it relates to the compliance program

When was the last time that the effectiveness of your Compliance Program was independently evaluated?

Category	
Within the last year	
No independent evaluation	
Within last three years	
Over three years ago	
Not Sure	

0% 5% 10% 15% 20% 25% 30%

Program managers cannot audit their own program effectiveness. This means the compliance officers cannot independently review or audit their own programs.

Concluding Comments

Compliance responsibilities continue to evolve and become more demanding. Furthermore, the survey results evidenced a continuing trend of compliance officers absorbing other functions as a cost-saving effort, resulting in added demands. Respondents reported these increases in duties and responsibilities, but in the face of all this, they continue to report that compliance office budget and staff is not increasing significantly. The size of compliance offices remains lean, with 75% having five or fewer staff and 33% having only one full- or part-time person. This suggests that many, if not most, compliance offices are being stretched thin to meet their obligations. Respondents indicated increased reliance upon vendor tools (hotlines, sanction screening, e-learning) to meet obligations. This is consistent with industry trends to focus on core responsibilities using internal staffing and use vendors to assist with ancillary or specialty needs.

Despite OIG recommendations, only 25% have their compliance programs independently measured for effectiveness, relying instead on self-assessments, checklist tools, internally generated surveys, and the like. Compliance officers, like all program managers, are responsible for ongoing monitoring of their programs to verify they are meeting obligations; however, they cannot perform ongoing auditing of the programs they operate. That must be done by parties independent of the operations of the program to have objective reviews. Too many are relying upon more informal and subjective analysis that lacks credibility for oversight bodies, rather than using independent evaluation methods to measure effectiveness.

Furthermore, evidence from the survey suggests that effectiveness is often measured in terms of output, rather than outcome. In addition, it is important to benchmark compliance program improvements. That was not in evidence in the survey, although the OIG calls for such measurements to evidence effectiveness of efforts.

Additional methods are suggested for gaining insights as to the effectiveness of the compliance program, including better methods of gaining employee feedback regarding understanding of the code of conduct, compliance policies, training lessons, use of communication channels, and overall trust in the program. Only a few organizations use professional testing and surveying for employee compliance understanding and commitment; most rely upon informal and internally generated processes.

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SAI Global helps healthcare organizations manage risk across the enterprise. SAI Global compliance solutions is an integrated, cost-effective governance, risk, and compliance platform, with applications designed to help healthcare providers manage the diverse set of risk and compliance challenges that they face today, including medical claims and denials, regulatory change management, third-party risk and contracts, and investigations of compliance incidents. SAI Global compliance solutions is a leading compliance solution among U.S. healthcare companies.

About Strategic Management Services

Strategic Management Services, LLC, (Strategic Management) was founded over 25 years ago by **Richard Kusserow**, the former DHHS Inspector General. It is a pioneer in healthcare compliance and was the first consulting firm to focus on it – before the government had even issued any formal compliance program guidance documents for the industry. The firm has assisted over 2,000 healthcare organizations with regulatory compliance services, such as the development of compliance program infrastructure, evaluation of compliance programs, standard of conduct development and reviews, compliance training programs, hotline setup, risk assessments, claims data analysis, assistance with the CIA requirements, IRO duties, and litigation support. Strategic Management also operates the Compliance Resource Center (CRC) that provides tools for compliance officers, including hotline services, policy development, e-learning, sanction screening, and compliance surveys. Strategic Management Services was the principal analyst of the data in this ninth annual Healthcare Compliance Benchmark Report.