

July 2015

Corporate Compliance

Initial assessment by: _____

Date: _____

In consultation with: _____

_____Date of previous
assessment: _____**ECRI's Risk Assessment Online**

ECRI's assessment tools provide a multidisciplinary perspective for identifying and managing risks related to this topic and other healthcare services. This web-based tool provides an easy-to-use, unbiased method to survey staff ranging from frontline nurses to organizational leaders. The tool generates reports, benchmarking data, and recommendations. clientservices@ecri.org

Ferretting out and preventing fraud and abuse by providers in federally funded healthcare programs has been identified as one of the federal government's highest priorities. The significance of implementing corporate compliance programs has been underscored by the multimillion-dollar penalties that healthcare organizations and providers have paid to resolve cases of alleged fraud and abuse brought by the government. The Patient Protection and Affordable Care Act of 2010 mandates the establishment of effective compliance programs for a broad range of healthcare providers. If they have not already, healthcare entities should implement corporate compliance programs as soon as possible. If a federal audit reveals noncompliance in the absence of a compliance program (including honest mistakes), the government will more than likely impose financial penalties. It will also mandate the creation of a more onerous compliance program than a voluntarily created program that was in effect before a government investigation. The government has unequivocally stated that only an effective corporate compliance program will be considered as a mitigating factor if it is going to seek sanctions against a healthcare facility.

Healthcare regulatory compliance deals with many areas that are regulated by agencies such as the Occupational Safety and Health Administration, the U.S. Environmental Protection Agency, and the U.S. Food and Drug Administration. Because government investigations and audits related to Medicare and Medicaid fraud and abuse are the areas of greatest financial vulnerability and significantly more intense enforcement activity, this self-assessment questionnaire (SAQ) focuses primarily on these areas. ECRI suggests that risk managers and corporate compliance officers complete this SAQ annually and that relevant sections be repeated more frequently, if necessary. Although this SAQ suggests basic components of a corporate compliance plan, it is not intended to be all-inclusive but rather is intended as a guide to some of those questions risk managers may wish to address.

The following sources were used to develop the questions in this SAQ; this list is not intended to be comprehensive:

- ▶ ECRI. Creating and maintaining an effective compliance and ethics program. *Health System Risk Manage* 2015.
- ▶ ECRI. Fraud and abuse laws. *Health System Risk Manage* 2015.
- ▶ Troklus D, Warner G. *Compliance 101*. Minneapolis: Health Care Compliance Association; 2011.
- ▶ Troyer GT. Corporate compliance: a risk management framework. In: Carroll R. *Risk management handbook for health care organizations*. 6th ed. Chicago: American Society for Healthcare Risk Management; 2011.
- ▶ U.S. Department of Health and Human Services. Office of Inspector General:
 - *Compliance program guidance for hospitals*; 1998.
 - *Supplemental compliance program guidance for hospitals*; 2005.

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

- U.S. Department of Health and Human Services Office of Inspector General, American Health Lawyers Association. Corporate responsibility and corporate compliance: a resource for health care boards of directors [online].
<https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf>

Yes	No	N/I*	N/A	Comments
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Structure

1.	Does the organization have a corporate compliance department or a designated individual with responsibility for compliance?					
2.	Does the organization have adequate staffing, resources, training, and authority to effectively carry out compliance efforts?					
3.	Does the healthcare organization's governing board oversee corporate compliance efforts?					
4.	Does the healthcare facility have a corporate compliance officer (CCO)?					
4.1.	Has the facility developed minimum criteria and qualifications for the CCO?					
4.2.	Is the CCO free from any conflicts of interest that can potentially hinder performance (e.g., responsibility for billing or preparing cost reports)?					
4.3.	Does the CCO have the authority to report directly to:					
	a. The chief executive officer (CEO)?					
	b. The board of trustees or the governing board of the healthcare facility?					
4.4.	Does the CCO have an effective working relationship with other key departments (e.g., internal audit, coding, billing)?					
4.5.	Does the CCO have the authority and resources to independently investigate all compliance-related issues that he or she determines to warrant investigation?					
5.	Has your healthcare facility provided sufficient funding for the compliance effort so as to ensure adequate performance of the corporate compliance program (CCP)?					
6.	Does the facility have a corporate compliance committee (CCC)?					
6.1.	Does the CCO oversee and monitor the CCC?					

* N/I stands for "Needs Improvement."



Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
6.2. Does the CCC meet regularly?					
6.3. Does the CCC include the risk manager?					
6.4. Do other key personnel (e.g., director of reimbursement, director of patient accounts, director of human resources, director of medical records, director of information technology) sit on the CCC?					
6.5. Is the CCP structured to reflect the unique needs of the healthcare facility (e.g., psychiatric facility, subacute unit)?					
6.6. Are adequate reporting systems in place that ensure that the CCO, CEO, and board of directors are kept informed about all compliance-related issues?					

Functions of the CCP

7. Do CCC members know that an operationally effective CCP may mitigate government administrative and criminal sanctions in the event that an audit or investigation reveals fraud and abuse?					
8. Does the CCP have a written document that contains basic philosophies and standards of ethical conduct,† as well as detailed policies for significant risk areas (e.g., coding and billing)?					
8.1. Is the code of conduct distributed to all directors, officers, managers, employees, and contractors?‡					
8.2. Is the code of conduct written in a manner that is comprehensible to all affected employees (i.e., translated as appropriate and written at an appropriate reading level)?					
8.3. Is an annual conflict-of-interest disclosure required of all directors, officers, managers, employees, and contractors?					
9. Does the facility communicate its CCP goals to all employees?					
9.1. Are all employees required to sign an acknowledgment indicating that they:					
a. Have received and reviewed a copy of the					

† The U.S. Department of Health and Human Services' OIG describes a facility's code of conduct as a basic set of standards that articulate the facility's values and framework for action; express a commitment to compliance by the governing body, management, and employees; summarize basic legal and ethical principles; and tell employees how to respond to practices that might violate the code of conduct.

‡ The term "employee(s)" in this SAQ also refers to independent contractors and other agents, including suppliers, of the healthcare organization.

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
facility's CCP and understand it?					
b. Agree to conduct themselves within the guidelines established by the CCP?					
c. Agree to report any suspected violation of the CCP to the CCO?					
10. Have the CCO and CCC reviewed the Office of Inspector General (OIG) compliance program guidelines applicable to the organization (e.g., hospital, physician practice, home health agency, clinical laboratory)? *					
10.1. Have the CCO and CCC reviewed OIG's published work plan for the current fiscal year?					
10.2. Does the CCO or CCC review all special fraud alerts issued by OIG?					
10.3. Does the CCO or CCC review advisory opinions that OIG issues?					
11. Is the status of the implementation process of the CCP routinely reported to the board of directors, CEO, and CCC?					
12. Does the CCO revise the CCP as the needs of the facility and relevant laws, statutes, and guidelines, including those affecting private payer plans, change?					
12.1. Does the CCP make provisions for training and educating all employees?					
12.2. Does the CCP require that a human resources exit interview program be implemented that solicits information from departing employees and staff regarding potential misconduct and suspected violations of policies and procedures?					
13. Is there a mechanism to perform background checks and identify individuals and entities that have been excluded from participation in Medicare and Medicaid that includes:					
a. Reviewing OIG's monthly listing of excluded individuals and entities (published in the Federal Register and available online at http://exclusionsoig.hhs.gov)?					
b. Using the National Practitioner Data Bank to check medical staff and independent contractors?					
c. Checking the General Services Administration's Excluded Parties List System (available online at https://www.sam.gov)?					

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
13.1. Is the mechanism for performing background checks stratified by type of employee (e.g., executive staff, licensed personnel)?					
14. Is there a mechanism to verify licensure and relicensing of employees?					
15. Does the CCP recognize that while it may provide services from an excluded party (i.e., provider), it may not submit bills for any services rendered by an excluded party, except in very limited emergency situations?					
16. Does the CCP address the healthcare facility's financial management by coordinating internal compliance review and monitoring activities, including periodic reviews of individual departments?					
17. Does the CCP have policies for retention and destruction of records of its activities, including outdated policies?					
17.1. Does the CCO realize that retention of outdated policies may be necessary as proof that the organization had a policy of adhering to prior regulations when those regulations were applicable, in the event that past practices are questioned?					
18. Is the CCO familiar with the section of the U.S. Sentencing Commission's <i>Federal Sentencing Guidelines Manual</i> that deals with the minimum elements of an effective CCP?					
18.1. Has the healthcare facility taken reasonable steps to achieve compliance with the U.S. Sentencing Commission's standards?					

Coordination and Communication

19. Does the CEO or other senior management communicate to all employees that the facility has a CCP to which it rigorously adheres?					
20. Has the healthcare facility implemented and published a reporting system that requires employees and agents to report known noncompliance and encourages reporting of suspected wrongful activity?					
20.1. Are employees permitted to make anonymous disclosures (e.g., suggestion box, post office box) to the CCO or his or her designee (e.g., the risk manager)?					
20.2. Is there a toll-free or otherwise dedicated					

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
phone number (hotline) that employees can call to:					
a. Report known or suspected violations?					
b. Request information or guidance (e.g., regarding billing and coding)?					
20.3. Are all reports to the hotline documented and monitored for trends over time?					
21. Are employees made aware of the importance of reporting known or suspected compliance violations?					
22. Has the organization clearly conveyed to employees that there will be no retaliation for reporting of known noncompliance with the CCP or for good-faith reporting of suspected violations?					
23. Are employees who communicate known or suspected violations informed that their confidentiality will be protected to the extent possible?					
24. Are lines of communication in place that help rather than hinder open and candid conversations with the CCO?					
25. Has the legal significance of adhering to the CCP been effectively communicated to all employees?					
26. Are all employees' compliance questions and the CCO's (or his or her designee's) responses (and corrective actions) documented?					
27. Does the facility investigate all potential cases of fraud and abuse in a timely manner?					
27.1. Are investigation results regularly reported to the governing body and relevant departments?					
27.2. Is the governing body actively involved in identifying recurring problems and taking actions to remediate the problems?					
28. Do billing, medical records, and other personnel inform the CCO or risk manager if they suspect an investigation is under way?					
29. Does the CCO conduct a root-cause or similar analysis of any discovered violations?					
29.1. If noncompliance is discovered, does the healthcare facility, to the extent possible, modify its internal procedures and its CCP to avoid repetition of similar activity, as well as to prevent and detect further noncompliance?					

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
29.2. Is a process in place to notify the appropriate government agency in a timely manner when a compliance violation requires reporting or self-disclosure?					
30. If the CCO either knows or suspects that the healthcare facility is under investigation by OIG, is legal counsel immediately notified?					
31. Are allegations of noncompliance communicated to the governing board and CEO?					
32. Is legal counsel asked to be present when someone presents information that implicates an employee in potential criminal or other illegal conduct so as to provide attorney-client privilege?					
32.1. Is there a written policy that clearly establishes the degree of disciplinary actions for any employee who violates the healthcare facility's CCP, including failure to report known noncompliance?					
33. Is it communicated to all personnel that appropriate disciplinary measures will be taken for violations of the CCP?					
34. Have all employees been informed that if they become cognizant of a problem and fail to report it, their employment may be terminated, and they may be legally liable for wrongdoing?					
35. Is it adequately communicated that the healthcare facility has a zero-tolerance policy toward fraud and abuse?					
36. Are all new personnel oriented to the CCP?					
37. Are all appropriate employees prepared for responding to a Medicare and Medicaid audit?					
37.1. Is there a detailed policy and procedure for coordinating an appropriate response to a government investigation?					
37.2. Are "compliance drills" (e.g., role playing) conducted to ascertain the level of preparedness for governmental audits or investigations?					
38. Have lines of communication and appropriate reinforcement of positive behavior been established to sufficiently minimize the risk of qui tam relators (i.e., whistleblowers)?					

Compliance Auditing and Monitoring

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
39.	Are audits performed of targeted areas (e.g., billing and coding departments) on a regular basis (e.g., every year)?				
39.1.	In addition to conducting annual audits, does the facility conduct periodic compliance program monitoring and communicate results to individuals responsible for operational performance?				
40.	Has the healthcare facility considered engaging the services of outside legal counsel to conduct a compliance audit?				
41.	Has the healthcare facility considered engaging the services of a competent external accounting or consulting firm to review billing procedures?				
41.1.	Is the organization aware that if an external consultant is requested by someone other than the facility's legal counsel, any information discovered may not be attorney-client privileged?				
42.	Are periodic audits conducted that specifically examine:				
	a. Relationships with third-party contractors?				
	b. Adherence to prohibitions on kickback arrangements?				
	c. Adherence to prohibitions of unauthorized physician self-referrals?				
	d. Appropriate coding?				
	e. Claim verification and submission?				
	f. Previously known or suspected weak areas?				
	g. The frequency of certain diagnostic codes?				
	h. Increased submission of claims for diagnosis with complications and comorbidities?				
	i. Treatment of protected health information (according to the Health Insurance Portability and Accountability Act of 1996 privacy and security rules)?				
	j. Target areas identified by OIG?				
43.	Do audits focus on current practices?				
43.1.	If an audit or monitoring reveals an incorrect practice, does that audit automatically go back as far as the statute of limitations (i.e., 6 years, which may be extended to 10 years)?				
43.2.	Does the CCO participate in the setting of				

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
priorities for internal audits?					
43.3. Does the CCO participate in the setting of priorities for external audits?					
43.4. Does the CCP include guidance regarding reporting and returning overpayments and notifying the government, intermediary, carrier, or contractor of the reason for the overpayment?					
43.5. If an audit or monitoring reveals wrongdoing or an overpayment, does the CCO realize that self-reporting and a paper trail may eliminate a qui tam (whistleblower) action?					
44. Does the facility's legal counsel have adequate experience in providing advice and counsel to healthcare organizations regarding laws and regulations intended to prevent fraud and abuse in healthcare?					
44.1. Does the facility's legal counsel have a good relationship with the U.S. Attorney's Office for the region?					
45. Does the CCO recognize the link between quality and compliance enforcement in light of financial relationships that implicate quality-of-care issues?					
45. Do managers and supervisors conduct and provide the CCO with performance evaluations regarding compliance from their respective areas for auditing purposes?					

Billing and Cost Reporting

47. Are all employees and agents responsible for billing trained on appropriate coding procedures?					
47.1. Are all employees who are responsible for billing familiar with appropriate billing procedures?					
48. Do all employees who are involved in billing recognize that:					
a. Billing for services not actually rendered is submission of a fraudulent claim under the federal False Claims Act (FCA)?					
b. The intentional submission of billing for services not "medically necessary" is considered a violation of FCA?					
c. "Intent" is not required for proof of an FCA violation?					
d. "Reckless disregard" or "deliberate ignorance" is the legal standard for civil FCA violations?					

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
e. Dual billing (e.g., billing both Medicare and the Department of Veterans Affairs) is a violation?					
f. "Samples" may not be billed for or otherwise sold?					
g. Billing for nonphysician outpatient services that were included in the hospital's inpatient payment under the prospective payment system (PPS) may be considered the submission of duplicate billing?					
h. False cost reporting is a violation?					
i. "Unbundling" otherwise inclusive laboratory tests or procedures is an FCA violation?					
j. Billing for discharge in lieu of transfer (i.e., when a PPS hospital transfers a patient to another PPS hospital and the transferring hospital charges the full diagnosis-related group [DRG] rate in lieu of the Medicare per diem amount) is a violation?					
k. Upcoding, or "DRG creep," is an FCA violation?					
49. Are all employees who are involved in billing educated on self-administered drugs that are not covered for out-patient claims?					
50. Is the billing department aware of appropriate coding for outpatient clinic and ambulatory surgery services?					
51. Are all codes periodically reviewed with a team approach, including coding experts, information services, clinical managers, and other appropriate personnel?					
52. Are ambulance services billed to Medicare only when no other means of transportation for a patient are available (i.e., in compliance with Medicare's medical necessity guidelines)?					
53. Does the facility check the statistical data regarding submission of billing (claims filing and cost information) for similar services from other facilities in the region with Medicare's data banks?					
54. Do the healthcare facility's written policies and procedures reflect and reinforce current federal and state statutes and regulations regarding the submission of claims and Medicare cost reports?					
55. Do billing policies and procedures specify that:					

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
a. All physician and other professional services are timely documented before billing?					
b. All claims should be submitted only when appropriate documentation supports the claim and that documentation is available for audit and review?					
c. Physician records, hospital records, and medical notes used for the submission of a claim are organized in a legible form that will facilitate audit and review?					
d. The diagnosis and procedures reported on the reimbursement claim should be based on the medical record and other documentation and that the documentation necessary for accurate coding is available to the coding personnel?					
e. Compensation for billing department coders should not provide any financial incentives to improperly code claims?					
f. Any billing consultants will have their references checked and that any suspicious billing practices will be questioned?					
g. Consultants are paid a flat fee, rather than an incentive arrangement (e.g., compensation linked to amount billed or revenue generated)?					
56. Are periodic reviews performed to ascertain the accuracy of the coding personnel (i.e., quality control mechanisms)?					
57. Are periodic reviews performed to determine the appropriateness of billing procedures?					
58. Does the healthcare facility follow appropriate billing practices for clinical laboratory tests (e.g., billing for laboratory tests only on completion of those tests)?					
59. Do coding employees accept diagnostic information only from qualified personnel?					
59.1. In the event that an individual who ordered a specific test has failed to provide the diagnostic information, is there a mechanism for billing personnel to contact the appropriate person to obtain that information?					
59.2. Does the CCP provide that claims should be submitted only for services the healthcare facility has reason to believe are medically necessary and that were ordered by a physician or other appropriate provider (e.g.,					

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
nurse practitioner, physician assistant)?					
60. Is there effective oversight of all billing practices and patterns within the facility, including tracking all instances when charges are waived or reduced and when something of value (e.g., a gift card) is given to reduce the probability of a liability claim?					
61. Does the healthcare facility follow appropriate billing practices regarding Centers for Medicare and Medicaid Services (CMS) payment rules for “serious preventable events” (e.g., pressure ulcers, catheter-associated urinary tract infection)?					
62. Are written policies and procedures in place to guide compliance with applicable federal and state laws, as well as regulations regarding cost reporting for both government-funded and private payer plans, and other reporting requirements including reporting to CMS as required by the Medicare secondary payer reporting statute?					

Physicians at Teaching Hospitals

63. Are physicians who are responsible for supervising clinical services provided to patients held responsible for ensuring that documentation supports the clinical services rendered?					
63.1. Do all physicians who are required to sign medical records do so, as appropriate, and ensure that evidence of services they provide or supervise is documented in patients’ medical records?					
63.2. Do all physicians document their presence during any procedure performed by residents for whom payment is sought?					
64. When a physician provides evaluation and management services, does the patient’s medical record include the basic elements of that service (e.g., history and physical, physician examination) in addition to documentation regarding any specific services that were performed and ordered by the physician?					

Training and Education

65. Does policy require all corporate officers, managers, employees, and independent contractor physicians to be trained initially and periodically (at least annually) regarding					
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Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

		Yes	No	N/I*	N/A	Comments
	the facility's CCP?					
66.	Does the CCO maintain training documentation, including content, the number and name of employees receiving compliance training, and the number of hours of training per employee?					
67.	Does the CCP training contain current information regarding fraud and abuse laws, including:					
	a. Coding issues?					
	b. Claims submission?					
	c. Illegal kickbacks?					
	d. Self-referrals?					
	e. Bad debts?					
	f. Credit balances?					
	g. Other appropriate compliance issues relevant to respective job functions?					
68.	Are training programs updated when regulations change or when new information (e.g., OIG advisory opinions, guidance) is issued?					
68.1.	Is the need for targeted training considered after a compliance question or problem is reported?					
69.	Are the reimbursement guidelines of private payers reviewed with appropriate medical, billing, and coding personnel?					
70.	Are employees encouraged to ask questions regarding the CCP?					
71.	Are appropriate incentives in place for employees to "buy into" the CCP?					
72.	Are employees internally rewarded (e.g., commendation in personnel records and performance appraisals, employee of the month, merit increase, eligibility for bonuses) for demonstrating positive behavior (e.g., communicating known or suspected violations, as well as legitimate billing and coding questions, to the CCO)?					
73.	For appropriate personnel, are the following areas included in the training program:					
	a. Reimbursement principles of government and private payers?					
	b. The general prohibitions against providing or receiving remuneration, or any form of compensation, made for the purpose of inducing referrals?					

Health System Risk Management Self-Assessment Questionnaire Corporate Compliance

July 2015

	Yes	No	N/I*	N/A	Comments
c. Confirmation of patients' diagnoses?					
d. Signing a form for a physician without authorization to do so?					
e. Falsifying or altering medical records?					
f. The provision of services or the prescribing of medications without proper authorization?					
g. Adequate and accurate documentation of all services rendered?					
h. The critical importance of reporting any known or suspected violations to the CCO or his or her designee?					
i. Issues relating to suppliers?					
74. Is there a minimum annual number of hours of training allocated based on the needs of specific positions (e.g., physicians, managers, coders, billing personnel)?					
75. For areas such as billing and coding, is training and retraining provided more frequently than on an annual basis?					
76. Do all physicians receive appropriate education on accurate and complete documentation?					
77. Is the participation of employees and staff, including physicians, mandatory (i.e., reflected in job descriptions) and considered a condition of employment or the provision of staff privileges?					
78. Do training programs involve employee participation (i.e., are they interactive)?					
79. Are arrangements made to facilitate training for weekend and night-shift workers?					
80. Is posttraining testing always performed to test the effectiveness of corporate compliance education?					

Assessment Completed By: _____ Date: _____

Question No.	Action Required	Responsibility	Target Date	Action Completed	
				Date	Initials

Health System Risk Management Self-Assessment Questionnaire
Corporate Compliance

July 2015

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