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NATIONAL ASSOCIATION OF  
Community Health Centers

**RISK  
MANAGEMENT  
SERIES**

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# Evaluating Your Corporate Compliance Program

Over the last ten years, Congress has appropriated hundreds of millions of dollars to federal agencies for the purpose of investigating health care providers suspected of fraud and abuse related to federal health care programs. In 2005, Congress established the *Medicaid Integrity Program* (MIP) at the Center for Medicare and Medicaid Services (CMS) to assist states in the prevention and detection of Medicaid fraud. More recently, Congress established the *Recovery Accountability and Transparency Board* to conduct oversight of programs funded under the American Recovery and Reinvestment Act (also known as the Stimulus bill).

Health care providers are increasingly at risk for fraud investigations, some number of which will result in civil and criminal sanctions, monetary penalties, and/or exclusion from participation in federal health care programs. Nonprofit health care organizations, including health centers, are no exception. In the recent past, health centers have made payments in the hundreds of thousands of dollars, and in at least one case, millions of dollars, to settle investigations with federal and state agencies. Those investigations that did not result in sanctions or monetary penalties against health centers still imposed a financial toll – defending a government audit or investigation can be expensive, requiring the professional services of legal counsel, accountants, and billing consultants, not to mention the diversion of staff time from other health center responsibilities.

***The development and implementation of an effective corporate compliance program is a critical risk management tool for health centers that can help reduce legal and regulatory exposures and related investigations.*** As defined in prior Information Bulletins,<sup>1</sup> a corporate compliance program is a system of internal controls designed to ensure that health care providers (including health centers) regularly evaluate and monitor their own adherence to applicable statutes, regulations, and program requirements. Although the decision whether to have a corporate compliance program is usually voluntary,<sup>2</sup> many health centers have concluded that it is the best way for a health center's board of directors to meet its Section 330 requirement to ensure that the health center is operating in compliance with all federal, state and local laws and regulations.<sup>3</sup>

***Yet once a corporate compliance program has been established, how does a health center know if the program is actually working to reduce legal and regulatory exposures?*** Like any other activity, a health center's compliance program needs to be evaluated on a periodic basis to determine whether it has been effective in identifying and correcting non-compliance. In addition, a health center's compliance program should be reviewed to determine whether it meets all of the federal government's expectations for compliance programs so that the health center will be eligible for more favorable treatment in the event fraud, false claims, or other violations of law are found.

This Information Bulletin addresses the steps that a health center can take to evaluate its corporate compliance program. The Bulletin:

- ◆ Describes the “Seven Elements” identified by the U.S. Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) for small physician practices, including health centers;
- ◆ Explains steps to prepare for evaluating the corporate compliance program;
- ◆ Identifies evaluation questions to assess implementation of the “Seven Elements.”

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1 In addition to legal and regulatory risks, a health center may face operational, financial, and health care provider specific risks. For more information about these other types of risk, see NACHC Information Bulletin Risk Management Series #1, *An Introduction to Risk Management Concepts* (Nov. 2002) and NACHC Information Bulletin Risk Management Series #8, *Implementing a Risk Management Program For Your Health Center* (Dec. 2003). To obtain copies of these Information Bulletins, please contact the NACHC Publications Department at (301) 347-0400, or download a copy from the NACHC website at <http://www.nachc.com/publications.cfm>

2 One exception to the voluntary nature of compliance programs is New York State, which requires certain Medicaid providers to develop and implement compliance programs. See 18 NYCRR Part 521 (2009). Health centers should consult with local counsel to determine the particular legal requirements in their state.

3 These regulations can be found at 42 C.F.R. § 51c.304(d)(3)(v) for community health centers and 42 C.F.R. § 56.304(d)(4)(vi) for migrant health centers. According to the Bureau of Primary Health Care (BPHC) within the Health Resources and Services Administration (HRSA), other types of Section 330-funded centers, such as those that service homeless people or residents of public housing, are not bound by these regulations but “may wish to look to these regulations for guidance.” BPHC Policy Information Notice (PIN) #98-23, Program Expectations.

*Health care providers are increasingly at risk for fraud investigations ... nonprofit health care organizations, including health centers, are no exception.*

## CORPORATE COMPLIANCE PROGRAMS – SEVEN ELEMENTS

As part of its efforts to involve industry in the government’s fight against fraud and abuse, the DHHS Office of the Inspector General has issued a number of “compliance program guidances” designed to promote the voluntary development and implementation of corporate compliance programs.

Of these, the most relevant guidance for most health centers is the *OIG Compliance Program Guidance for Individual and Small Group Physician Practices*.<sup>4</sup> That guidance recognizes that small physician practices (including many health centers) do not have the financial or staffing resources to implement a full scale, institutionally structured compliance program as described in other compliance program guidances, and provides considerable flexibility in the program’s design and implementation.

Nevertheless, all of the OIG’s compliance program guidances include seven elements that should be included in every compliance program. These seven elements are based on criteria contained in the *Federal Sentencing Guidelines*, which are used to determine whether an organization has in place an effective program to prevent and detect violations of law. If the organization meets those criteria, then the federal courts are permitted to impose a reduced fine. The following summarizes each of the seven elements.

### **The Seven Elements of a Corporate Compliance Program**

1. Designation of a Compliance Officer or Contact
2. Conducting Internal Monitoring and Auditing
3. Implementing Written Standards and Procedures
4. Conducting Appropriate Training and Education
5. Developing Open Lines of Communication
6. Responding Appropriately to Detected Offenses and Developing Corrective Action
7. Enforcing Disciplinary Action through Well-Publicized Guidelines

## Designate a Compliance Officer or Contact —

### CORE ELEMENT ONE

The OIG compliance program guidance states that, ideally, one member of the organization’s staff needs to accept the responsibility for coordination and oversight of compliance activities for the organization. A compliance officer should be designated and assigned personal responsibility for overseeing the implementation and day-to-day operations of the compliance program. A compliance officer should be a high-level official who:

- ◆ Has direct access to the organization’s board of directors and Chief Executive Officer (CEO); and
- ◆ Provides reports to the board of directors (or a committee of the board) regarding the activities of the compliance program.

<sup>4</sup> 65 Fed. Reg. 59434 (Oct. 5, 2000).

## Conduct Internal Monitoring and Auditing —

### CORE ELEMENT TWO

The OIG recommends that periodic audits be conducted (at least once each year) to determine whether:

- ◆ The organization's written standards and procedures are being followed; and
- ◆ The organization's claims submission practices comply with applicable requirements.

Particular attention should focus on:

- ◆ Whether bills are accurately coded and reflect the services provided as documented in the medical records;
- ◆ Whether documentation is being completed correctly;
- ◆ Whether services or items provided are reasonable and necessary; and
- ◆ Whether or not incentives for unnecessary services exist.

## Implement Written Standards and Procedures —

### CORE ELEMENT THREE

The OIG encourages the use of *written* standards and procedures as an effective tool for addressing areas of risk. Such written standards and procedures should be designed to reduce erroneous claims and fraudulent activity within an organization by:

- ◆ Reflecting current and legal requirements applicable to high areas of risk; and
- ◆ Establishing internal controls to prevent the occurrence of false claims and other abuses.

## Conduct Appropriate Training and Education —

### CORE ELEMENT FOUR

The OIG states that training and education is an integral element of an effective compliance program. The OIG recommends:

- ◆ Providing education and training on the compliance program generally and targeted training for employees whose work involve specific risks, such as staff involved in coding and billing; and
- ◆ Training and education should occur after a compliance problem has been identified.

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## Develop Open Lines of Communication — CORE ELEMENT FIVE

The OIG emphasizes the importance of open communication between the organization's compliance officer and its employees and contractors. The OIG recommends two methods to encourage open communication:

- ◆ Establishing written confidentiality and non-retaliation policies to encourage communication and the reporting of incidents of potential fraud; and
- ◆ Developing a procedure whereby employees may report potential compliance issues and seek clarification from the organization's compliance officer in the event that a question arises, *i.e.*, anonymous hotlines, e-mail, and bulletin boards.

## Respond Appropriately to Detected Offenses and Develop Corrective Action — CORE ELEMENT SIX

The OIG guidance emphasizes the need to respond appropriately to detected violations through:

- ◆ Investigating allegations; and
- ◆ Disclosing violations to appropriate government entities.

The OIG identifies specific actions that can be taken as part of the “decisive” steps to correct significant violations. These may include, as appropriate:

1. Develop a corrective action plan;
2. Return any overpayments;
3. Report violations to the government; and/or
4. Refer violation to law enforcement authorities.

## Enforce Disciplinary Standards through Well-Publicized Guidelines — CORE ELEMENT SEVEN

The OIG recommends establishing, and publicizing, procedures for enforcing and disciplining individuals who violate the law or applicable standards in order to add credibility and integrity to the compliance program. These disciplinary procedures should be consistent and appropriate for the violation, but should also be flexible enough to account for mitigating or aggravating circumstances. The OIG identifies the following disciplinary actions as appropriate:

- ◆ Warnings (oral);
- ◆ Reprimands (written);
- ◆ Probation;
- ◆ Demotion;
- ◆ Temporary suspension;
- ◆ Termination;
- ◆ Restitution of damages; and
- ◆ Referral for criminal prosecution.

## PREPARATION STEPS FOR THE EVALUATION

### Determine Frequency of the Evaluation

The annual work plan for every corporate compliance program should include a year-end review of the compliance program. The timing of the review should allow the results of the evaluation to inform the compliance program activities and budget for the coming year. The evaluation should: 1) assist the health center's board of directors in budgeting sufficient resources and overseeing operation of the compliance program; and 2) influence the priorities, methods, and activities of the compliance program.

For example, if there has not been a single employee complaint or question utilizing the "open" channels of communication, the chosen channels should be re-evaluated.

### Consider Staffing for the Evaluation

The evaluation of the compliance program may be done by health center staff or outside experts, but there are advantages and disadvantages to each. The use of health center staff may be more economical and less intrusive, but may be less objective than outside

experts. On the other hand, the use of outside of experts may have more credibility with a health center's board of directors and provide the ability to benchmark against other health centers.

To obtain the best of both approaches, a health center may want to alternate years between using health center staff and outside experts.

### Determine the Scale of the Evaluation

In evaluating your compliance program, it is essential to remember that the OIG recognizes that organizations will have different capabilities for staffing and financing compliance programs. As a consequence, a compliance program for one health center may be inappropriate for another. For example, it is reasonable to expect that larger health centers with more complex programs or multiple lines of business and larger budgets will need to allocate more funding to compliance programs than smaller ones. If a smaller health center has had serious compliance issues, it will have to invest more in compliance programming (and evaluating the program) than a similar health center that has not had such problems.

### Establish Evaluation Criteria

Consider evaluating your compliance program on the basis of at least two criteria:

**Incorporation of all seven elements** – All corporate compliance programs, regardless of the size of a health center, should include all seven elements of a compliance program, as described above. Each element is critical to the overall success of the program. Implementing written standards and procedures, for example, will be difficult without providing sufficient training and education related to them; auditing and monitoring compliance will have little impact unless the organization responds to detected offenses and enforces disciplinary action.

**Effectiveness of the compliance program** – Because an ineffective compliance program may give a false sense of security, your evaluation should also determine whether the means chosen to implement each of the seven elements has been effective, and overall, whether the compliance program has been effective at identifying and reducing compliance risks. For example, if your health center has required annual compliance training for all employees, then you should assess what percentage of employees have actually received the training *as well as* whether the employees possess a minimum level of



knowledge about the compliance program. A low percentage of attendees at the training may suggest a need to enforce disciplinary guidelines, while a low level of knowledge might suggest the need to consider another teaching approach.

## Gather Information

**Corporate compliance program documents** – To conduct the review of your compliance program, first you should compile all of the key documents related to the program in one place. Although not all health centers will have all of the following documents, key compliance documents include:

- ◆ Board Resolution Establishing the Compliance Program
- ◆ Compliance Program Policies and Procedures
- ◆ Compliance Program Description
- ◆ Compliance Officer Job Description
- ◆ Compliance Program Work Plan
- ◆ Compliance Program Annual Report
- ◆ Compliance Committee Charter and Minutes (staff)
- ◆ Compliance Committee Charter and Minutes (board of directors)

**Interviews with key individuals** – After reviewing the documents described above, you should conduct interviews of the key individuals involved in implementing the compliance program. Interviews with the key individuals will be particularly important for health centers that do not have all of the compliance documents described above. Key individuals include:

- ◆ Chair of the Board's Compliance Committee
- ◆ Chief Executive Officer
- ◆ Compliance Officer
- ◆ Compliance Program Staff

Based upon the size of the health center, there may be additional individuals who would be knowledgeable about the compliance program. These may include:

- ◆ General Counsel
- ◆ Human Resources Director
- ◆ Chief Financial Officer
- ◆ Chief Operating Officer

## CONDUCTING THE EVALUATION

Once a health center has compiled all the necessary information, it can begin to evaluate its compliance program. Below are key questions for each of the “Seven Elements” that can be used to evaluate how well the health center has implemented each element of a corporate compliance program.

### Designate a Compliance Officer or Contact —

#### CORE ELEMENT ONE

The designation of a single person to accept responsibility for the compliance program and manage its day-to-day operations is critical to ensuring that the compliance program remains visible, active, and accountable. In addition, it enables the health center's board of directors and CEO to receive information about the activities of the compliance program from a single person, without confusion regarding whose job it is to address particular aspects of the program. It is worth mentioning that designating a single person to accept responsibility for the compliance program is not the same thing as a single person accepting responsibility for the organization's compliance with legal requirements. Rather,

an organization's compliance is the responsibility of all of the employees and contractors of the organization, as well as board members, not just a single individual.

### Key Evaluation Questions

- ◆ Are compliance responsibilities clearly delegated to specific, senior individual reporting to the CEO and the board to ensure oversight and accountability?
- ◆ Does the individual have personal responsibility for overseeing the implementation and day-to-day operations of the compliance program?
- ◆ Is there a committee of senior staff members (frequently known as the compliance committee) who meet regularly with the compliance officer and help get the work done?
- ◆ Are sufficient subject matter experts assigned compliance oversight responsibilities to appropriately cover all relevant risk areas?

## Conduct Internal Monitoring and Auditing —

### CORE ELEMENT TWO

An audit is used to test whether an organization is complying with its policies and procedures or other legal requirements and can help identify areas that are not in compliance and are in need of corrective action. Typically, audits are structured as independent assessments performed on a retrospective basis. In contrast, monitoring is an activity performed on a concurrent basis by operational staff to ensure that their activities comply with internal procedures or other legal requirements.

### Key Evaluation Questions

- ◆ Have audits been conducted to monitor compliance?
- ◆ Do the audits focus on key risk areas, *e.g.*, whether bills are accurately coded and accurately reflect the services provided (as documented in the medical records); that documentation is being completed correctly; that services or items provided are reasonable and necessary; and whether or not incentives for unnecessary services exist?
- ◆ Do the audits demonstrate compliance with internal written policies and procedures?

- ◆ Have audits revealed fewer errors in areas where written policies have been implemented?

## Implement Written Standards and Procedures —

### CORE ELEMENT THREE

The implementation of written standards and procedures ensures that employees (and contractors or other agents of the health center) have clear expectations for their conduct. Health centers should have written standards of conduct, or a “Code of Conduct,” that:

1. Expresses the organization's commitment to ethical and legal behavior;
2. Describes the health center's conflict of interest policy; and
3. Offers information on the health center's compliance program and compliance reporting mechanisms.

In addition, the health center should have written standards and procedures addressing the organization's principal risk areas to ensure that legal requirements are distilled into clear, workable directions. Last but not least, the compliance program should have written policies and procedures that address each of the seven elements of its compliance program.



### Key Evaluation Questions

- ◆ Does the organization have a Code of Conduct that describes the compliance program and consequences of non-compliance?
- ◆ Is the Code of Conduct applicable to board members, employees, contractors and volunteers?
- ◆ Does the health center screen job applicants before initiating an employment relationship and periodically thereafter to assure they have not been excluded from participating in federal health care programs and/or federal contracts (excluded by the OIG and/or the General Services Administration (GSA))?
- ◆ Has an internal risk assessment been conducted to identify relevant risk areas?
- ◆ Does the organization have written policies and procedures in the key risk areas?
- ◆ Does the organization's compliance program have written policies and procedures?
- ◆ Are the organization's policies and procedures clearly written?

- ◆ Are applicable policies and procedures easily available to employees and contracted staff?

## Conduct Appropriate Training and Education —

### CORE ELEMENT FOUR

Training and education helps to promote understanding of the organization's compliance program, legal requirements, and written policies and procedures. Annual training events create an important opportunity for a health center to convey its organizational values, including its commitment to ethical and legal conduct. The training on the organization's compliance program should explain the significant legal risks faced by the organization and the important role that employees and contracted staff have for maintaining compliance. In addition, specific training should be provided to employees whose job functions raise significant risks for the health center, *i.e.*, coding and billing staff, practitioners, and finance staff.

### Key Evaluation Questions

- ◆ Does the health center document its training and education efforts?
- ◆ Does the health center conduct annual training and education to employees and contracted staff about the compliance program?
- ◆ What percent of employees and contracted staff receive training regarding health center's compliance program?
- ◆ Is there additional training for specific staff, *e.g.*, coding training for appropriate employees?
- ◆ Has the training resulted in a certain level of knowledge of the areas trained?
- ◆ When employees are interviewed during an internal audit, do they understand what the law and the health center's policies and procedures require?
- ◆ Is additional training provided to employees after findings of non-compliance?

## Develop Open Lines of Communication — CORE ELEMENT FIVE

To facilitate detection of potential non-compliant conduct, it is necessary for all employees to feel comfortable in reporting compliance issues. That is easier said than done. Many employees will be concerned about how reporting potential compliance issues will reflect on them individually as well as fearing adverse reactions from other employees and superiors. Consequently, it is critical that health centers create an environment in which employees do not have reason to fear retaliation from reporting or that their reports will not be taken seriously.

### Key Evaluation Questions

- ◆ Have internal mechanisms for reporting compliance issues been established by the health center?
- ◆ Is there a clear “open door” policy between employees (and contractors) and compliance staff?
- ◆ Are there conspicuous notices posted in common areas and/or the development and placement of a compliance bulletin board where everyone in the organization can receive up-to-date compliance information?

- ◆ Does the health center use a hotline or email to facilitate communication?
- ◆ Are employees aware of the reporting system?
- ◆ Is an anonymous reporting option made available to employees?
- ◆ Is a confidential reporting option made available to employees?
- ◆ Has the health center received reports of suspected noncompliance?
- ◆ Are reports analyzed for trends?

## Respond Appropriately to Detected Offenses and Develop Corrective Action — CORE ELEMENT SIX

For a compliance program to be effective, the compliance officer must take steps to correct any potential or actual occurrences of non-compliance. As part of this process, a health center should investigate credible allegations to determine their scope, causes, and seriousness. If possible, non-compliant conduct should be halted immediately and any ongoing harm should be minimized. Any corrective actions taken to address non-compliance should aim to reduce the likelihood of similar instances

of non-compliance occurring in the future.

### Key Evaluation Questions

- ◆ Does the health center have a process for investigating reports of suspected non-compliance?
- ◆ Has the health center reviewed reports of non-compliance and taken appropriate investigative steps to determine whether a significant violation of applicable law or the requirements of the compliance program has indeed occurred?
- ◆ Does the organization have a policy for responding to government investigations?
- ◆ Are serious findings of investigations reported to senior managers and/or the board?
- ◆ Can the health center document a prompt response to reports of non-compliance and any corrective action, as appropriate?
- ◆ Have corrective audit plans been put into place to address compliance findings?
- ◆ Has the health center returned any overpayments, made a report to the government, and/or a referral to law enforcement authorities?

## Enforce Disciplinary Standards through Well-Publicized Guidelines —

### CORE ELEMENT SEVEN

In most cases, employees intend to follow the rules of their organizations, to the extent such guidance is provided, and they want to meet the expectations of their employers. However, in some cases it will be appropriate to discipline individuals who violate standards or policies. Enforcing disciplinary standards is important not only to give the compliance program credibility, but also to demonstrate a health center's integrity and commitment to compliance and desire to prevent recurrence.

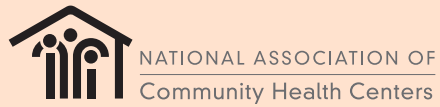
### Key Evaluation Questions

- ◆ Does the health center have enforcement and disciplinary procedures to ensure that violations of its policies will result in consistent and appropriate sanctions?
- ◆ Does the health center publicize those procedures in in-house training and procedure manuals?
- ◆ Has the health center documented any non-compliant conduct?
- ◆ Has the health center disciplined offending individuals and if so, how?
- ◆ Is compliance an element of every employee's job description (and every contract, as applicable), performance reviews, and incentive compensation decisions?

## CONCLUSION

An evaluation is an important part of implementing an effective corporate compliance program. To conduct that evaluation, you will need to know what efforts the health center has made to implement each of the seven elements of its compliance program as well as whether those efforts have been successful, *i.e.*, the outcomes of those efforts. For health centers that have new compliance programs, efforts may be more feasible to evaluate than outcomes at this point.

*As the compliance program matures, the focus for new compliance programs should move from effort to outcomes.*



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