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Community Health Centers

### **Important Content Note:**

This technical assistance resource was developed prior to the August 2017 release of the Health Center Compliance Manual by the Health Resources and Services Administration's (HRSA) Bureau of Primary Health Care (BPHC). The BPHC Compliance Manual, issued August 2017, indicates where PINS, PALs and other program guidance are now superseded or subsumed by the BPHC Compliance Manual.

See: <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf>

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## Information Bulletin #18

Updated January 2016

# Conducting a Health Center Risk Assessment

**P**rior Information Bulletins have discussed the importance of having a **Risk Management Program** to reduce a health center's exposure to loss, described risk management methods to control or avoid risks,<sup>1</sup> and explained expectations of the Health Resources and Services Administration ("HRSA") that health centers seeking deeming under the Federal Tort Claims Act implement risk management systems.<sup>2</sup>

One of the key components of risk management is conducting the risk assessment. In general, risks that are not being adequately addressed by current risk management activities and that involve substantial exposure to the health center should receive highest priority for corrective action and monitoring.

***The purpose of a "risk assessment" is to identify the most serious risk areas facing a health center through a formal analysis of how well it is addressing potential risk areas.***

This Information Bulletin focuses on the risk assessment process. In particular, this Information Bulletin:

- ◆ Explores the reason health centers should to conduct risk assessments;
- ◆ Identifies the key steps to conduct a risk assessment.

At the end of this Information Bulletin, readers will have an opportunity to apply what they have learned by examining a sample risk profile.

In this information bulletin of the National Association of Community Health Centers (NACHC), the term "health center" refers to public or private nonprofit entities that: (1) receive grants under Section 330 of the Public Health Service Act (Section 330), including Sections 330(e), 330(f), 330(g) and 330(h) (collectively "Health Center Program Grantees"); and (2) entities that have been determined by the Department of Health and Human Services (DHHS) to meet the requirements to receive funding without actually receiving a grant ("health center look-alikes").

1 NACHC Information Bulletin Risk Management Series #1, An Introduction to Risk Management Concepts and NACHC Information Bulletin Risk Management Series #8, Implementing a Risk Management Program For Your Health Center.

2 Federal Tort Claims Act Health Center Policy Manual at 17.

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## RISK MANAGEMENT

In a prior Information Bulletin, we identified three basic steps to overall Risk Management. These are:

**1. IDENTIFY WHO SHOULD HAVE INPUT INTO RISK MANAGEMENT IMPLEMENTATION.**

Name a Risk Manager to be responsible for coordinating the risk management program. Ideally, this person should have the support of a risk management (or compliance) committee and staff at all levels. An appropriate choice for this person could be the health center's compliance officer because compliance is an aspect of risk management.

**2. DETERMINE WHAT AREAS OF RISK EXIST.**

Identify, assess, and prioritize areas of operation that pose or may pose a risk to a health center.

**3. PLAN HOW TO IMPLEMENT A RISK MANAGEMENT PROGRAM.**

Once the risks have been identified and prioritized, a health center can take actions to control the potential exposure such as eliminating or preventing the exposure, minimizing or reducing the potential loss, or transferring the potential loss by contract or insurance.

This Information Bulletin focuses on Step Two – determining what areas of risk exist.

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## WHY HEALTH CENTERS SHOULD CONDUCT RISK ASSESSMENTS

The scholar Erasmus declared “Prevention is better than cure.” This is not only sound advice for health center clinicians, whose work involves the risk of medical malpractice, but for all health center staff. Medical malpractice is only one of myriad risks facing health centers.

Health center staff should understand risks in all areas of business operation, and likewise, governing board members should understand risks related to their responsibilities to establish priorities and policies and to exercise general oversight of the health center project. The risk assessment is a critical component of a health center's overall risk management program. The benefits of a formal risk assessment include:

**Minimizing Risk** – The risk assessment process will allow a health center to identify high risk areas so that it can develop appropriate responses to mitigate or prevent the effects of those risks.

**Conserving Resources** – Although a risk assessment requires up-front investment in terms of time and resources, in the long run a risk assessment will benefit a health center by identifying areas where the health center is losing or may lose resources (financial and otherwise). Once the health center staff recognizes that these risks exist, and that the health center is committed to addressing them, they are likely to be more motivated to address them.

**Creating Sound Management Practices** – As part of the risk assessment, the Risk Manager should interview personnel at all staff levels of the health center. Employees should be asked whether they perceive any risks associated with clinical and management practices. This will enable the Risk Manager to assess perceived risks and advise on what practices might need to be altered to manage those risks.

**Improving Operational Efficiency** – In the day-to-day operation of any health center, sometimes it is easy to forget about best practices that can make the health center operate more efficiently. A comprehensive risk assessment will look at all aspects of the health center, and assess whether high risk functions, like billing, communications, and finance, might be operated more efficiently. This will benefit the entire organization.

**Meeting the Government’s Compliance Program Expectations** – While the above reasons should be sufficient to convince any health center that a risk assessment is in its best interest, probably the most compelling reason to conduct a risk assessment is to meet the government’s compliance program expectations. In 2000, the Office of Inspector General (“OIG”) for the U.S. Department of Health and Human Services (“HHS”) developed the Compliance Program Guidance for Individual and Small Group Physician Practices that aimed to reduce the submission of erroneous and fraudulent claims by such providers. As part of that compliance program guidance, the OIG strongly recommends conducting a risk assessment.<sup>3</sup>

*“One of the most important things in making [a] determination [of what organizational threats need to be addressed] is a listing of risk areas where the practice may be vulnerable”.*

— Office of Inspector General<sup>4</sup>

## KEY STEPS IN CONDUCTING A RISK ASSESSMENT

The frequency with which a health center conducts a risk assessment will vary based on resources available and amount of support that staff contributes to the process. We recommend that all health centers endeavor to conduct a comprehensive risk assessment every two to three years. Certain high risk areas should be assessed more frequently. For example, the OIG recommends that an audit of claims submission, one part of a comprehensive risk assessment, should be conducted on an annual basis.<sup>5</sup>

There are three main steps to completing a risk assessment, each of which is discussed in greater detail below:

1. Determine the scope of the risk assessment.
2. Identify risks to the health center.
3. Prioritize risks.

3 OIG Compliance Program Guidance for Individual and Small Group Physician Practices, 65 Fed. Reg. 59,434 (Oct. 5, 2000) available at [www.oig.hhs.gov/authorities/docs/physician.pdf](http://www.oig.hhs.gov/authorities/docs/physician.pdf). Health centers are not specifically identified in the Guidance as a type of small group physician practice. Of the Guidances issued by OIG, this Guidance is probably the most pertinent to health centers.

4 Id at 59438.

5 Id. at 59437.

## 1. Determine the Scope of the Risk Assessment

In this first step, a health center should determine the scope of the risk assessment by identifying the types of risk that it wants to evaluate during the risk assessment. Because there are many types of risks facing a health center, it is helpful to group risks with other risks of similar type. Risks may be broken down into the following categories:

**Operational** – Includes the possibility of loss to buildings, office equipment, personal property, vehicles, and other physical assets of the health center.

**Legal liability** – Analyzes risk that the health center will be sued such as: tort liability for non-clinical injuries to patients, employees and other parties; liability for breach of contract; and liability arising from prohibited conduct or practices. These potential liabilities include those related to the health center's obligations as a corporation (e.g., breach of fiduciary duties), as a provider (e.g., submission of false claims), and as an employer (e.g., wrongful termination).

**Compliance** – Considers issues related to compliance with federal, state, and local legal requirements, i.e., health center requirements under Section 330 of the Public Health Service Act and its implementing regulations, third-party payor billing and coding rules, and in requirements under 45 C.F.R. Part 75 related to the maintenance of appropriate documentation of cost reasonableness, allocability, and allowability.

**Financial** – Addresses concerns related to health center solvency, grants management issues, sound procurement practices, appropriate fiscal management standards and cash drawdown policies, officer and employee bonding, reserves and investments.

**Clinical** – Relates to provider-specific risks such as medical staff credentialing, medical malpractice,<sup>6</sup> patient safety, informed consent, medication administration, experimental procedures, clinical research, medical records, and other areas that affect patient care and service.

### Hidden Risks

In all of the categories above, be sure to consider hidden risks that may not be immediately apparent. Such concerns may include negligent supervision or improper selection of the health center's staff and volunteers, violation of reporting laws, theft or destruction of materials that are worth more to the health center than their insurable replacement value, and environmental damage from toxic waste on health center property.

### Focus of the Assessment

Assessing all of the above categories of risk facing your health center in a single risk assessment may overwhelm other administrative responsibilities. To ease this burden, the Risk Manager might consider focusing on only one or two categories of risk at a time, i.e., legal liability and compliance.<sup>7</sup> However, the Risk Manager should be certain to address the other categories at some future point. Focusing on a single risk category to the exclusion of assessing other types of risk will neglect other potential high risk areas. Over

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6 For more information on when the Federal Tort Claims Act applies to your health center, and for additional guidance on insurance coverage for your clinicians and for the health center, see NACHC Information Bulletin Risk Management Series #11, Beyond FTCA: Purchasing Insurance Coverage to Protect Your Health Center from Liabilities.

7 Although a health center may want to narrow the categories of risk assessed at any one time, we recommend a broad assessment within each risk category. For example, if a health center conducts a compliance risk assessment, we recommend performing a comprehensive "baseline" assessment of the health center's current level of compliance in all departments or functional areas.

time, conducting a comprehensive risk management program that addresses all of the risk categories will provide the greatest benefit to the health center.

### Common Health Center Risks

After determining which category (or categories) of risk the health center wants to assess, the Risk Manager should consult various external sources to learn about what risks commonly affect health centers. These sources will help keep the Risk Manager informed of the key risks. For example, for legal and regulatory risks, sources to consult might include:

- ◆ Government and regulatory general guidance, especially OIG industry guidance
- ◆ A-133 Compliance Supplement for Consolidated Health Centers
- ◆ Fiscal intermediary bulletins or local coverage determination policies, including local Medicare contractor's notice or policy on handling of claims
- ◆ Professional or industry newsletters or notices, such as free alerts sent to users of *HealthCenterCompliance.com*
- ◆ Medicare conditions of participation

With this knowledge, the Risk Manager will have a better sense of the risks facing his or her own health center.

**Common Risk Areas** – identified by the OIG in the Individual and Small Group Physician Practice Compliance Guidance:

- ◆ Coding and billing
- ◆ Documentation
- ◆ Reasonable and necessary services
- ◆ Improper inducements, kickbacks and self-referrals

### **Risk Areas Identified in A-133 Compliance Supplement<sup>8</sup> for Health Centers**

- ◆ Ensuring that health centers are providing all services required under applicable law
- ◆ Ensuring that the health center governing board is in compliance with DHHS regulations
- ◆ Ensuring that a proper audit of the health center is conducted
- ◆ Ensuring adequate oversight of program income
- ◆ Conducting appropriate financial reporting

This is only a partial list of high risk areas for health centers to evaluate; the Risk Manager should consult the sources suggested herein to increase his or her understanding of high risk areas.

8 Office of Management and Budget, Consolidated Health Centers, in OMB Circular A-133 Compliance Supplement, 4-93.217-4 (Mar. 2014).

## 2. Identify Risks to the Health Center

Once the Risk Manager has determined the categories of risk to assess and is familiar with the most common types of risks within those categories, the Risk Manager can begin to identify the areas of operation that currently pose a high risk to the health center. Although the Risk Manager coordinates the risk assessment, it is essential that he or she receives the support and assistance from staff throughout the health center. Staff should make themselves available to the Risk Manager for interviews and to provide requested documents.

### Review of Internal Documents

As an initial step, the Risk Manager should review internal documents to get a better sense of possible health center deficiencies. Documents to review should include:

- ◆ Previous external audit and consulting reports – The Risk Manager can look at audit reports (governmental or independent), external reviews (e.g., Joint commission [formerly JCAHO], HRSA Operational Site Visit Reports) or internal compliance or grievance reviews to determine what risks were identified in the past, and whether changes were subsequently made to respond to any concerns raised in the audit. Problem areas that still have not been addressed may require extra attention.
- ◆ Risk Management training course syllabi and attendance records

Among other things, the Risk Manager should consider how often trainings occur, whether they teach compliance with current laws, and whether attendance is properly documented. In addition, the Risk Manager should determine how individuals are selected to participate in trainings.

### Interview Health Center Personnel

To identify risks, the Risk Manager should interview individuals who manage or work in key functional areas of the health center. A list of sample questions to ask health center employees follows:<sup>9</sup>

#### ◆ **Management team-specific questions**

1. What is your perception of how well we comply with federal, state, and local laws and regulations?
2. What do you think are the major operational risks?
3. Are there proper methods in place to ensure that appropriate corrective actions are taken when audits reveal health center deficiencies?

#### ◆ **Questions for any health center staff**

1. Are there certain risks that often go overlooked?
2. What risks are less likely to happen but might have a major impact on the health center, should they occur?
3. Is there any inefficiency (financial, managerial, or other) in your functional area? Are there ways to prevent the identified inefficiencies?
4. Would you say that our health center has a “culture of compliance?” Why or why not?
5. How are you trained on compliance and broader risk management techniques?
6. How are new regulations or policies identified and distributed? Are you and your colleagues quick to comply with new health center policies, or is there a tendency to continue to function under old practices and to refuse to adapt?

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<sup>9</sup> Some of these questions were adapted from Brian Riewerts, *Baseline Compliance Risk Assessments*, in *The Health Care Compliance Professional's Manual*, ¶ 40,140 (2005).

**Practical Tip:**

When preparing documents for the risk assessment, avoid listing past instances of activity that might constitute an admission of liability for the health center. Instead, describe the exposure as a potential or possible event. For example, rather than stating “clinicians discussed protected health information (“PHI”) in a public setting”, state “inappropriate disclosure of PHI is a potential risk.”

Following the interviews, the Risk Manager should return to internal documents to determine whether the health center’s policies and procedures are consistent with what he or she heard in interviews. Are there any important policies that are not being followed? Are there any significant procedures that the Risk Manager heard of that are not documented?

**3. Prioritize Risks**

The final step in the risk assessment is to prioritize among the many risks facing the health center. By ranking the risks, a health center can determine which ones pose the greatest threat to the health center and therefore merit attention. Knowing which risks have the greatest chance of adversely affecting the health center will also help managers strategically allocate resources to address the most important risks. There are two main ways to prioritize the risks to your health center: quantitative and qualitative. While we discuss both here, the qualitative method is probably best suited to the needs of most health centers.

**Quantitative Method**

The Quantitative Method assigns each risk a numeric value based on the following calculation:

$$\text{Risk (R)} = \text{Loss value (L)} \times \text{Probability (P)}$$

Under this method, the higher value that R receives, the greater is the threat of the risk.

The quantitative model can be quite effective in certain settings where an organization is attempting to develop highly accurate and specific models. For example, the Food and Drug Administration will use the quantitative model when assessing the safety of new drugs or the specific threat of disease from food-borne pathogens.<sup>10</sup>

We do not encourage use of the quantitative model because it can be very time consuming and labor intensive, and requires the use of sophisticated statistical software. Further, if your health center has limited resources, it can be very difficult to determine with much accuracy the variables of probability and loss value.

<sup>10</sup> For examples of the use of quantitative models in drug safety, see <http://www.fda.gov/Drugs/DrugSafety/default.htm>. For examples of the use of quantitative models in food safety, see <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm#>.

## Qualitative Method

Most health centers will find the Qualitative Method a more useful method for prioritizing risks. It is easier to implement, requires fewer resources, and allows for more input from staff. There are two main steps to the qualitative method for risk prioritization.

1. **Determine the likelihood of occurrence and severity of each risk** – For each risk identified, consider these two factors:

- Likelihood of occurrence – A health center should determine, based on notes from the document reviews and interviews with health center personnel, the likelihood that each risk would occur. Categorize this likelihood as remote, possible, or probable.
- Severity – Consider the impact that the risk would have on the health center if it were to occur. Would the health center lose \$1,000? \$10,000? \$1 million? Would it threaten the health center’s licensure (as applicable) or cause the federal government to withhold funding? Categorize the severity as moderate, serious, or severe.

2. **Construct a risk profile** – Once a health center has determined the likelihood of occurrence and the severity of each risk, it can construct a risk profile. Chart each risk on the graph below to determine if the risk should be categorized as Low, Medium, High, or Critical. Those risks identified as high and critical will demand the most immediate attention from the health center.

Impact Severity	<b>Severe</b>	<b>Medium</b>	<b>High</b>	<b>Critical</b>
	<b>Serious</b>	<b>Low</b>	<b>Medium</b>	<b>High</b>
	<b>Moderate</b>	<b>Low</b>	<b>Low</b>	<b>Medium</b>
		<b>Remote</b>	<b>Possible</b>	<b>Probable</b>
Likelihood of Occurrence				

### Sample Risk Profile

#### Facts identified by the Risk Manager

- ◆ Two months ago, the State Medicaid Agency conducted an audit of twenty-five paid claims for services provided by the ABC Community Health Center. Ten of these claims were determined to be problematic.
  - ✓ The documentation for three claims involved missing medical records.
  - ✓ Four encounters were billed at service codes higher than supported by the medical record.
  - ✓ Three claims forms were missing the physician’s signature.

The Medicaid Agency will seek repayment related to these ten claims. Based on the high failure rate, the Medicaid Agency also plans to conduct a second, larger audit within twelve months.

- ◆ ABC has established Health Insurance Portability and Accountability Act (“HIPAA”) policies and procedures to safeguard private health information. It held mandatory HIPAA trainings for all medical group staff prior to hire, yearly training updates, and specialized training for medical records staff. In an interview, the Privacy Officer acknowledged that the health center’s privacy policies are not always followed. Staff members are known to discuss patients’ health issues within earshot of other patients, medical records have been inadvertently faxed to the wrong number, and the Privacy Officer receives at least one written HIPAA complaint each month.
- ◆ Human Resources (“HR”) informs the Risk Manager that a staff member recently resigned after “having enough” of a certain senior physician at ABC. HR confides in you that the physician was the subject of a sexual harassment complaint ten years ago. He was disciplined at the time, and because there were no complaints since, HR believed that he had changed his behavior. Although he has been spoken to in the past, ABC never took formal action against him. He is adored by his patients.

#### Risk Profile<sup>11</sup>

Impact Severity	<b>Severe</b>	<b>Medium</b>	<b>High: Unauthorized disclosure of PHI</b>	<b>Critical: Improper coding and billing</b>
	<b>Serious</b>	<b>Low</b>	<b>Medium: Sexual harassment</b>	<b>High</b>
	<b>Moderate</b>	<b>Low</b>	<b>Low</b>	<b>Medium</b>
		<b>Remote</b>	<b>Possible</b>	<b>Probable</b>
Likelihood of Occurrence				

11 These prioritization levels simply help to illustrate the final step in the risk assessment. If you were to do a similar analysis, you might rank these differently, based on interviews with staff members and overall health center operations

## CONCLUSION

Risk management involves three basic steps – identifying WHO should have input into risk management implementation; determining WHAT areas of risk exist; and planning HOW to implement the risk management program. The second step – determining what areas of risk exist – is known as the “risk assessment.” The purpose of a risk assessment is to identify the most serious risk areas facing a health center through a formal analysis of how well it is addressing potential risk areas.

- ◆ There are many **reasons for conducting a risk assessment**, including minimizing risk, conserving health center resources, creating sound management practices, improving operational efficiency, and, perhaps most importantly, meeting the government’s compliance program expectations, which are focused on minimizing the submission of erroneous and fraudulent claims by such providers.
- ◆ While the frequency with which health centers conduct their risk assessments will vary, there are three main **steps to completing a risk assessment** which all health centers should follow to minimize future exposure: determining the scope of the risk assessment; identifying the risks to the health center; and prioritizing the risks.
- ◆ After the risks have been prioritized and the most critical and high level risks have been identified, the Risk Manager should implement the final step of a risk management program– **risk control activities**. This involves implementing methods to:
  - ✓ Control risks
  - ✓ Develop strategies to finance corrective action for risks that materialize
  - ✓ Incorporate risk management as part of the health center’s operating plan
  - ✓ Provide ongoing risk monitoring.

***The purpose of a risk assessment is to identify the most serious risk areas facing a health center through a formal analysis of how well it is addressing potential risk areas.***

## Best Practice Checklist for Conducting a Risk Assessment

- ✓ Is a full risk assessment conducted every two to three years? Is an audit completed annually?
- ✓ Is the risk assessment coordinated by a Risk Manager
- ✓ Does the Risk Manager have the full support of management and staff?
- ✓ Does the Risk Manager review industry materials and government guidance to understand what risks a health center is most likely to face?
- ✓ Does the Risk Manager focus on one or two categories of risk at a time, but conduct a comprehensive baseline assessment within risk categories?
- ✓ Once the critical and high risks are identified, does the Risk Manager move quickly to apply risk management techniques in order to help address/correct problems and, ideally, prevent them from occurring in the future?

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