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Am I covered? and other questions to ask about insurance

By Patrick J. Hickey, CPCU, RPLU, MBA

Patrick J. Hickey (patrick.hickey@9thstreetinsurance.com) is a self-employed Insurance Consultant living in New York City.

Is insurance available to cover regulatory claims that arise from actual or alleged violations of the False Claims Act (FCA), Stark Law (Stark), and Anti-Kickback Statutes (AKS)? If so, who is covered under the insurance? Are the limits of the insurance sufficient to cover large-dollar cases?

Asking these and other relevant questions will not only help improve your understanding of the coverage you have, it will also help make sure you get the coverage that is best for you and your organization.

What is the risk we need to insure against?

All providers that bill for services under Medicaid, Medicare, or other government programs are exposed to the risk that they may run afoul of rules and regulations governing participation in these programs. These risks pertain not just to the organizations but also to individuals and employees within the organization. In fact, in recent years, there have been increasing efforts to hold individuals personally accountable to FCA, Stark, and AKS regulations.

Beginning with the release of a memo titled “Individual Accountability for Corporate Wrongdoing” (also known as the Yates Memo^[1]) in 2015, the U.S. Department of Justice (DOJ) has signaled increased focus in identifying and prosecuting (civilly and criminally) individuals involved with fraud and misconduct. The memo directed prosecutors to “focus on individual conduct from the inception of any investigation” and was subsequently supported by new rules put in place by Deputy Attorney General Rod Rosenstein in 2018. Although this policy may be aimed at senior executives, and recent prosecutions of healthcare CEOs might make headlines, compliance professionals and other employees remain exposed to this risk.

This trend toward individual accountability means that those involved in regulatory compliance should ask questions about insurance and understand the current coverage in place. In particular, compliance professionals should:

- Become informed about available insurance coverage;
- Be encouraged not to settle for the basic and limited coverage provided in most insurance policies; and
- Understand how they can use effective compliance programs to get the best insurance protection for the organization and its employees.

Does my organization have coverage for these risks?

If your organization carries insurance for your board members and directors (D&O insurance), the answer to this question is probably yes. Most D&O policies issued to healthcare providers include some level of coverage for these types of claims. Additionally, some level of coverage might also be included in your organization’s medical

malpractice policy or policies issued to individual providers. Your organization might even have purchased a separate policy designed to specifically cover this risk. Several types of insurance policies might actually provide coverage for this risk, including:

- Directors and officers liability insurance
- Healthcare regulatory liability insurance
- Physicians regulatory insurance
- CyberPro and regulatory medical billings insurance
- Billing errors and omissions insurance

There are many different types of policy forms and very little uniformity in the language and coverage of many policies covering this risk. Of course, each organization is different, and what works for one healthcare provider might not be right for others. For these reasons, special care and attention is needed when evaluating the coverage in place for your organization. In the following sections, I have chosen to focus primarily on D&O liability insurance, because there are several benefits to using this policy as the basis of coverage.

Who is covered?

In most D&O and stand-alone policy forms, the definition of an “insured” is rather broad and generally includes employees. However, this is not always the case, and some policies limit coverage to executive officers, board, or committee members only. The following is standard wording contained in most D&O policies:

Insured persons means all persons who were, now are or shall become:

- a director or officer of the company;
- any employee; and
- the functional equivalent of a director, officer, or employee in the event the company is incorporated or domiciled outside the United States.

What is covered? Defense costs, fines and penalties, and return of funds

In some cases, coverage will include costs arising from expenses in defending claims but not for any fines and penalties that may result. Other policies will include coverage for fines and penalties with certain limitations; however, coverage for return of funds is generally not available.

What is covered? Specific activities and regulations

With some policies, the carrier broadly defines the scope of coverage to include “government regulations,” which can include the Health Insurance Portability and Accountability Act (HIPAA), Emergency Medical Treatment and Labor Act (EMTALA), and other regulations governing healthcare providers. However, because there may be coverage for violations of these rules in other policies, it’s common for carriers to specify that D&O coverage applies only to FCA, Stark, and AKS. The following is typical language that limits coverage in this way:

Regulatory Wrongful Act means any actual or alleged:

1. act, error, omission, misstatement, misconduct, fraud, reckless disregard or negligence committed by an

Insured in the performance of, or failure to perform, any of the following activities in the Medicaid, Medicare,

Federal Employee Health Benefit or TRICARE programs:

- a. procedure coding;
 - b. bill, claim, cost report or data submissions; or
 - c. the calculation of managed care payments;
2. offer, acceptance or payment by any insured in exchange for any patient referral(s), in violation of any state, local, or federal law; or
 3. offer, acceptance, or payment by an insured in violation of any state, local, or federal anti-kickback law.

Again, because HIPAA, EMTALA, and other risks are generally covered elsewhere, this definition may be appropriate, depending on your specific coverage.

How much coverage? Limits of liability, retentions, and coinsurance

This might be the most overlooked and yet most critical area of coverage. Limits provided vary significantly according to the type of policy or coverage, but in most D&O policies they are \$1 million or less. The limits are also affected by retentions or deductibles that must be paid before coverage kicks in. Further there is often a coinsurance provision that requires the insured to pay some part of every dollar of the loss. In some policies this is as high as 50%.

When evaluating the amount of coverage, organizations and individuals should consider the exposure being covered. Defense of regulatory matters can easily cost several million dollars and, of course, fines are frequently in the tens of millions of dollars. The intent of the coverage is to protect the assets of the organization and its employees. Obtaining the right structure of limits, retentions, and coinsurance, within the budget constraints of the organization, is perhaps the most important objective in this process.

What else? Other terms, conditions, and exclusions

There are, of course, many other factors to consider when evaluating coverage. Some examples of provisions that should be examined include:

- **Coverage for claims brought by commercial payers** – Most carriers will include this coverage, but occasionally it must be requested.
- **Pay-on-behalf versus indemnification wording** – There are pros and cons to each of these approaches but, generally speaking, smaller or mid-sized provider organizations prefer to have the carrier assume defense and pay on their behalf.
- **Exclusions for violation of readmission guidelines or formulas** – Some forms include restrictions such as these, which should be negotiated out of the policy.
- **Coverage for risk mitigation expenses** – Some policies will provide a limit of coverage to pay for expenses related to pre-claim investigation costs and other expenses related to risk mitigation.

These are just a few of the many provisions that should be part of a comprehensive, side-by-side review of the

coverages available to the organization. The comparison should be aligned with priorities of the organization and, in most circumstances, there are tradeoffs that are made to arrive at the best terms achievable. Of course, “what’s achievable” is determined by the level of attention and expertise that is involved in the insurance purchasing process, as well as the effectiveness of the organization’s compliance program and risk profile.

Effective compliance programs and applying for broader coverage

Underwriters who are knowledgeable about regulatory compliance risks will ask questions about your compliance program and your overall regulatory risk profile. In fact, most healthcare D&O applications will contain a section on this subject and, generally speaking, your ability to show that your compliance program is active, robust, and effective is directly correlated to the coverage options that will be available.

When seeking broader regulatory coverage or higher limits of coverage, either under a D&O policy or a separate stand-alone policy, more information on your compliance program is generally required. For example, some stand-alone applications for healthcare regulatory insurance will ask for general information on the organization and its structure, and they will also require detailed information on the compliance function, billing and coding procedures, and physician arrangements. Similar questions are also asked in supplemental D&O applications for increased regulatory coverage.

The applications for broader coverage can be intensive and, in some cases, are more than 50 questions long. Typical questions in a stand-alone application include:

- Does the applicant have a compliance officer?
- What is the reporting structure for compliance?
- How often is the board informed on compliance-related matters?
- Has the board formally adopted a compliance policy and program?
- If so, does the compliance program include:
 - Education and training
 - Internal billing audits
 - External billing audits
 - External legal consultant
 - External coding consultant
- Are certifications obtained from all employees to indicate that they have read and understood all compliance policies?
- Has the applicant conducted an external compliance effectiveness analysis?
- Does the applicant screen employment applicants and existing healthcare providers who render services against the Department of Health and Human Services Office of Inspector General’s List of Excluded Individuals/Entities?
- Does the applicant screen employment applicants and existing healthcare providers against the General Services Administration’s List of Parties Debarred from Federal Programs?

- Does the applicant have an annual compliance audit/analysis work plan that includes billing, coding, and documentation compliance?
- Does the applicant have a conflict of interest policy?
- Does your organization have a code of conduct policy?

Although underwriters will also ask about your organizational history of investigations or disclosures, if your company has had previous activity or prosecutions, it is not always an obstacle to obtaining the right coverage. More important to underwriters is the risk profile of the healthcare provider on a go-forward basis. Providers who have been through a significant investigation or settlement might actually be considered a better risk to underwriters.

One last point about the application process—although it is always important to be complete and thorough with your application, it can help to take the application a step further by arranging for a meeting or a call with your underwriter to discuss your compliance program in greater detail. If you have a great story to tell, you should make sure it gets heard.

Final thoughts

You need to ask. Compliance professionals and their organizations are at significant risk of financial loss associated with regulatory enforcement activities. The current trend of individual accountability puts compliance officers and others at greater personal risk. Asking the right questions and pushing for good answers is imperative to protect the organization, its employees, directors, and officers. Compliance professionals who ask these questions and are able to document compliance program effectiveness are generally able to obtain much broader coverage that provides real protection.

Takeaways

- Compliance professionals can be held personally accountable for noncompliance.
- Insurance is available to cover the risks of noncompliance.
- Coverage varies in scope.
- With no uniformity, it's important to ask questions and press for answers.
- Compliance programs may help organizations obtain better risk insurance coverage.

¹ Department of Justice, Office of the Deputy Attorney General, Memorandum from Sally Quillian Yates, Sept. 9, 2015. <https://bit.ly/2nLMPa4>.

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