



AdvaMed

Advanced Medical Technology Association

Reprinted from *Business Solutions* • February 26, 2003

Improving Your Risk Profile May Result in Insurance Savings

By Jill Wadlund & Frank Goudsmit

After years of relatively low insurance prices, the insurance industry today is experiencing a hard market. For insurance buyers, that means policies may cost more and have more restrictive terms than they did a few years ago. But underwriters who specialize in providing insurance to the medical technology industry don't view all medical device firms through a single lens. Medical device companies that demonstrate the highest level of performance get the best terms and pricing in any market. Those with an average to poor "risk profile" may have more difficulty finding affordable insurance that meets their unique needs in a hard market. To determine its level of performance and assess the risk that a medical device firm represents, a knowledgeable medical technology underwriter will take a good, hard look at all aspects of the business, from sprinklers to sales training.

The insurance underwriter's job is to evaluate risk and determine how much of a particular risk he or she is willing to assume on behalf of the insurance company and at what price. The underwriter also works closely with experts in loss control to try to improve the loss exposure. How a company manages its business and its exposures to loss can distinguish it as a "better risk" or a "worse risk." Better risks qualify for lower rates and more generous terms from top-flight insurance companies. An insurer with an intimate knowledge of the medical device industry will want to find out what you do and how you do it. Then the underwriters will assess how you conduct your business relative to other firms in the industry.

Here are some of the qualities—both philosophical and technical—that an experienced medical technology underwriter will look for in evaluating a medical device firm. By striving to incorporate these qualities into your business, you can make your medical device company a better risk—which can translate into savings on your insurance program.

A long-term view of the business. Medical technology underwriters try to discern if a company takes a long-term or short-term view of its business. It's an easy bet that short-term thinkers will create more problems for an insurer than long-term thinkers will. Management that makes decisions to achieve short-term benefits may, for example, rush a product to market and end up recalling it later. Long-term thinkers invest in risk management and avoid shortcuts that may improve the bottom line in the next quarter but could threaten the business's long-term success.

Best practices. Underwriters are looking for medical device companies that strive to achieve the best practices in their standard operating procedures rather than abiding by the letter of the law. Companies that do only the minimum that regulations require are more likely to experience more and greater losses, whether as the result of a tainted product that can't be sold or, in the worst case, a defect that contributes to the injury or death of a patient. Underwriters will investigate how many regulatory violations a company has been cited for, the nature of those violations and how the company has responded to them. Evidence that a medical device firm provides quick and candid responses to the regulators' inquiries tells the underwriter something about the company and its attitude toward regulatory compliance; a history of unanswered letters that result in warning letters from the regulators sends an entirely different message.

A commitment to patient safety. Talking about patient safety is one thing; evidence of a true commitment to doing something about it is another. Does the company provide honest and full disclosure about the risks and benefits of its products to the healthcare community? Has it committed resources and authority to safety surveillance groups that monitor adverse events and provide unfettered support from senior management? Underwriters look closely at these kinds of quality control monitoring.

Proactive design. Underwriters look carefully at the design process. Do the company's design engineers engage in systematic and thorough analyses to try to anticipate how the

product will be used and how it might be misused and then build controls designed to prevent inappropriate use? Companies dedicated to human design engineering are less likely to face product liability problems.

Employee training. A company's policies and procedures are only as good as the people who institute them. Underwriters want to know what kind of messages employees are receiving from senior management. Training should include an emphasis on safety in the workplace, such as ergonomic workstations, guarded machinery and proper fire prevention. Field training is also critical; for example, is the training program for salespeople so focused on production and incentives that they feel encouraged to promise something the product can't deliver or to downplay its risks? An effective sales training program should emphasize the importance of candid and objective dissemination of information.

Well-run clinical trials. When a medical device firm is engaged in clinical trials, an underwriter will want to see a well-documented informed consent process and a form that is written clearly and simply, while also accurately outlining any potentially harmful effects.

A facility-protection philosophy. An underwriter will want to see that a medical device firm has a prudent facility protection philosophy that drives all of its engineering efforts and its analysis of facilities it intends to build or acquire. Underwriters will look, for example, at a company's security system; the controls it has to protect clean rooms from potential breaches; and how flammable chemicals are stored and dispensed. Are the sprinkler systems in the warehouse appropriate for the type of commodities stored there? The underwriter will also look for evidence that the company engages in ongoing testing and maintenance of its protection systems.

Supply chain redundancy. Medical device companies risk losing millions of dollars in business income if a key supplier experiences a fire or other disaster. However, many are unaware that they can insure against the business income they lose when the supplier can't provide critical materials. Underwriters that provide this coverage want to know that their policyholders have thoroughly analyzed their supply chain dependencies and have identified alternative suppliers where possible.

Business continuity plan. A business continuity plan is a risk management road map. By developing a business continuity plan and then regularly testing and updating it, a medical device firm demonstrates a strong commitment to the long-term survival of its business. During the process of developing a plan, a company assesses its vulnerabilities

to a disaster, takes steps to control them and then prepares for the possibility that one will occur anyway. This includes everything from instructions for responding to an emergency to backup plans that will get operations running again and restore the business to normal in as little time as possible. Medical device firms that have thought through their exposures and how they would get back in business are much more likely to minimize losses in a disaster, improving their risk profile from an underwriter's point of view.

Small Companies, Strong Controls

More than 80 percent of medical technology companies have fewer than 50 employees and little or no sales revenue, according to AdvaMed. These small businesses, which often have limited personnel and budget resources, may find it more challenging to operate at the peak of best practices. Nonetheless, small medical device firms can do a lot to improve their risk profile.

Exceeding regulatory requirements does not have to be onerous or prohibitively expensive. When underwriters evaluate small companies, they look for the right attitude. Has the company demonstrated a commitment to do the best it can with the resources available to it? What kinds of messages are employees getting from management when it comes to patient safety? A sophisticated safety surveillance system may be beyond the means of a small company, but underwriters will know if a CEO is dead serious about getting feedback from doctors and patients for incorporating safety improvements into the design.

Insurer as Business Partner

In the end, an experienced medical technology underwriter is looking for medical device companies, whether large or small, that view their insurance carrier as a business partner. Insurance companies that know a lot about the medical technology industry can help medical device companies implement effective loss prevention strategies and improve their defense posture in product liability cases. Insurers can help medical device companies incorporate safety into the design of new facilities and evaluate exposures to property, liability and business income losses. Good medical technology insurance companies put enormous effort into understanding the businesses they insure and emerging trends that will affect them. Their experience with claims and litigation makes them a clearinghouse of information that comes back to clients in the form of their risk assessment, as well as loss control recommendations and services.

How does an underwriter know if a company views its insurer as a business partner? That's easy. Companies that shop for a better price each year raise a red flag. An under-

writer also learns a lot about a medical device firm from its willingness or unwillingness to cooperate during the risk assessment by providing access to decision makers and detailed answers to their questions. Medical device firms that view their insurer as a business partner will provide early and regular communications about potential problems. The companies that represent the best risk are those that want to take advantage of the insurer's expertise in risk management and loss control. They want more information from their insurer, though they need it less.

Choosing an Insurer

Medical device firms should be as choosy about their insurer as their insurers are about them. Your agent or broker should be able to help you find an insurer that receives top ratings for financial strength and claims-paying ability, that has an excellent reputation for handling claims and that understands the unique needs of a medical technology company. For example, most insurance policies pay a business income loss until the property that has been damaged is physically restored; but, medical device companies may want to look for a medical technol-

ogy insurer that pays business income losses until there is an operational restoration of the business to cover the time it takes for the FDA to recertify the facility to begin manufacturing again.

The relationship between a medical device company and its insurer should not be an adversarial one or a distant one. Medical device companies should look for top-quality insurers that specialize in providing coverage to medical technology companies and demonstrate an interest in creating a business partnership. An insurer that specializes in the medical technology industry has the ability to develop policies that respond to the specific needs of medical device firms, provide services that help them reduce losses, lower insurance costs in both soft and hard insurance markets and ultimately help the company succeed in the marketplace.

Jill Wadlund, vice president, Chubb & Son, and casualty manager, life sciences, can be reached at Jwadlund@chubb.com or 908-572-4697. Frank Goudsmit, assistant vice president, Chubb & Son, and property & international manager, life sciences, can be reached at fgoudsmit@chubb.com or 908-572-4416

