

MEDICAL DEVICE SALES REPS – ARE THEY INSURED FOR NEGLIGENCE?

Medical device sales representatives play an important role in the delivery of an assortment of products to physicians and their patients. Medical reps are often present in the operating room and provide advice during surgery involving medical devices, such as cardiac pacemakers, spinal implants and artificial hips and knees.

Medical device manufacturers usually purchase product liability insurance to provide coverage for failure of their product resulting from negligent design or manufacturing. These product liability policies are certainly intended to cover negligent product failure, but do they cover the activities of employed or contracted medical device sales representatives?

CASE EXAMPLE

A medical representative present in an operating room during a knee replacement is asked by the surgeon to retrieve a knee kit for the procedure. The rep pulls the wrong knee from the hospital's inventory of his company's product. The physician implants the knee and the patient suffers severe injury as a result of the mistake.

In this case the orthopedic knee replacement is not a defective product. The injury resulted from the medical representative making an error and the physician failing to catch the mistake before implanting the device. Is this loss covered by the medical device manufacturer's product liability insurance? Is the answer to this question different if the medical representative is a contractor, not an employee?

Courts have traditionally held that product instructions and service manuals are an integral part of a product. That theory can be extended to medical representatives who are acting under the direction, supervision and control of the medical product manufacturer. Their advice and instructions are tied to the product.



Many insurance companies have added specific language to the product liability policies that grant coverage to both employed and contracted medical representatives. Employees are covered "for acts within the scope of their employment or while performing duties related to the conduct of your business..."

Contractors, sometimes referred to as “1099 employees,” can be covered in a product liability policy as “medical product sales contractors.” Typical insurance language will provide coverage for “any Life Science Product Sales Contractor or organization while acting on your behalf, pursuant to a written contract or agreement between you and such contractor which requires you to provide insurance such as that provided by this policy...” In this sample policy language there is a requirement of a written contract or agreement between the product manufacturer and the contractor that obligates the device manufacturer to provide liability insurance. In the absence of a written contract or agreement, there probably isn’t any coverage for the negligent acts of the contractor. If it is the intent of the manufacturer to provide liability insurance for contracted medical reps, be sure that the obligation is spelled out in a contract or agreement. (Note: some insurers do not require a written contract or agreement as a condition of coverage.)

Some medical device manufactures elect not to cover life science product sales contractors on the manufacturer’s product liability policy. These companies require the medical sales representative to obtain his/her own individual policy. This type of coverage is available through specialty insurance markets. However, this approach may result in a conflict at the time of a claim where the contractor and manufacturer are insured separately. The contractor’s insurer will attempt to transfer the blame to the manufacturer and vice versa. A coordinated defense of a product liability claim may result in a more favorable outcome for both the manufacturer and the contractor.

Some insurance policies that cover contract sales reps may exclude coverage for the “sole negligence” of the contractor. A contractor that doesn’t have an individual policy and relies on the manufacturer’s policy for liability protection, may find himself without coverage if a law suit is brought against only the contractor. It is rare that a suit would only name the contractor, but be aware of this coverage limitation.

Most medical product liability policies will contain an exclusion for any liability arising from “direct medical services” or “professional services.” The intent of this policy language is to exclude the medical professional liability (malpractice) exposure. For example, insurers do not intend to cover the liability for a medical sales representative who steps into a surgical suit and illegally assists a physician with a surgical procedure. Medical reps may provide advice during surgery but are not permitted to lay hands on a patient.

PROCTORING

The policy exclusion of “professional services” may also exclude coverage for proctoring services. Proctoring services refers to surgical training, assistance, coaching or guidance provided to a physician or surgeon by the manufacturer’s employed or contracted



It is common practice in some foreign countries for medical sales representatives to actually assist during surgery, including hands-on activities. If your U.S. policy is intended to cover worldwide products liability and contains a “professional services” exclusion, there could be a gap in coverage for claims involving direct patient contact.

medical proctor. If a device manufacturer employs medical proctors, the professional services exclusion should be modified to include the proctoring services as insured activities.

Hospitals frequently require medical device manufacturers to provide evidence of professional liability insurance before allowing medical representatives to supply products or services in the hospital setting. This requirement is applied inconsistently across the health care industry. We assert that a product liability policy that includes coverage for the activities of employed or contract medical representatives should satisfy a hospital's insurance requirements. It is not necessary for a device manufacturer to purchase a separate medical professional liability policy, because there is no doctor/patient relationship and direct patient contact by a medical representative is illegal and therefore excluded from coverage.

Policy language that provides coverage for employed and contracted medical sales representatives varies. It is important for medical device manufacturers to first decide if they intend to cover medical reps on their product liability policy. A risk review performed by a qualified insurance broker can help determine if the risk exists and advise on how to properly handle risk transfer by contract and/or insurance. Once the risk review is completed, examine carefully the policy language regarding medical sales representative and proctoring services to assure proper risk mitigation.

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