

DISTRIBUTORS AND HOSPITAL CONTRACTS: LET THE SELLER BEWARE

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Distributors of sophisticated medical devices have, for the past several years, found it increasingly necessary to enter into agreements with hospital and surgi-centers. In some cases, the customers have presented the distributor with an agreement and said that unless the agreement was signed, the distributor could not do business with the healthcare provider.

The opposite situation is when the distributor and customer have negotiated an arrangement for the distributor to sell certain products to the customer and the distributor offers the customer the agreement. In those situations, the distributor is often agreeing to sell disposables to the hospital for a certain length of time at a guaranteed price. The distributor may be selling the device for which the disposable is used to the hospital; it might be consigning that device to the hospital at no charge; it might be leasing the device for a term or on a per-use basis.

Such agreements, whether they are those that are pre-conditions for selling to the hospital, or are to sell a specific group of products to the hospital, must be considered carefully. They can contain any number of pitfalls for the distributor. There are also matters that must be negotiated carefully. In those situations when the hospital presents the distributor with an agreement giving the distributor access to the hospital, unless the distributor is carrying a product which is absolutely essential and for which there is no competition, the hospital may be extremely resistant to modifying its own contract. The distributor wants the right to sell to the hospital, and the hospital always wants low prices and maximum protection from liability. In those situations, the distributor must make a dollars and cents decision as to whether it makes economic sense to deal with that particular healthcare provider.

Where the distributor is entering into an agreement to sell a particular product or group of products, generally disposables, to the hospital at a set price, the distributor's bargaining position is greater, since the

hospital has already decided to use that product.

The following is a checklist of what to consider when entering into a contract to provide product or to be allowed to provide product to a healthcare provider. Some of these issues are more significant in one rather than both of the types of arrangements, but every one of these issues might play some role in either type of agreement:

Price. What are you selling or being allowed to sell, and at what price? How and under what circumstance can the price be modified, either by the distributor or by the hospital? Are there caps (such as a maximum dollar or percentage) on price increases? What happens if your principal raises its price? Can your principal raise its price during the period that the contract is in effect? Under what circumstances can the hospital insist that the price can be decreased? Is there what is known as a "most favored nations clause," that is, a provision that says that if you sell the same product to another hospital at a lower price, you must offer that product to this hospital at that lower price?

Length of Contract. Is your contract with the hospital exclusive or does it just allow you to sell, but does not guarantee that the hospital must buy? How long is the contract to last? Under what circumstances can the contract be renewed? What happens to the price if the contract is renewed? Watch out for contracts that say that they are for a term of years but have a provision that says that either party may terminate the contract with or without cause on thirty days' notice. Such a clause makes the entire contract meaningless, since the hospital can always say either you change your price or your terms and conditions or we will terminate the contract in thirty days.

Effect of Reimbursement. What is the hospital's obligation if its reimbursement by third-party providers for the product you are selling changes? Is its price somehow tied to reimbursement? Is payment tied to the

time reimbursement is received? Another issue is when are you paid. Are you paid within a certain amount of time after the product is delivered, after you invoice for the product, or when the hospital is paid for the product and, if the third-party payer does not pay for the product, is the hospital still required to pay you?

Minimum Quantity. Is the hospital required to purchase a minimum quantity of the products that you are selling per year, per month or on some other basis? If you are entering into a contract to be allowed to sell into the hospital, does the hospital have any obligation to purchase product from you and, if so, what is that obligation? What happens if the hospital fails to purchase the minimum quantity of products that it is to buy? Must it buy products to make up the difference, pay some amount of money to compensate you for the shortfall, or is the only remedy the right to terminate the contract? Also, what, if any, penalties are there to the hospital if it simply does not pay you when it is supposed to? There should be an interest charge on payments beyond whatever your terms are. Whether you enforce such interest payment is another matter.

Indemnification. One of the major issues in any contract between a hospital and a distributor is who is responsible for what in the event that there is a third-party claim for negligence, product liability or the like. Naturally, there should be insurance, but who has to carry insurance, how much insurance must be carried, and does one of the parties have to name the other as an additional insured under its policy should also be addressed. It should be recognized that insurance, regardless of how much insurance is being carried, might not be enough for a really serious injury. There are also times when, for example, there is a claim of an intentional injury. Insurance may not cover such a claim. One of the things that you must be careful about is whether the owner of the distribution company is personally responsible for the carrying out of the contract and, therefore, might be personally liable for injuries resulting from the sale of the products. The distributor also must be careful since, even if it is added as an additional insured on its principal's liability policy, that policy will probably not protect the distributor if it is the distributor's negligence that causes the injury. Also,

there is no guarantee that the principal will have such insurance in effect at the time of an accident.

Issues Involving Your Manufacturer. Does your contract with the hospital have provisions that protect you if a manufacturer stops producing the product that is the subject of the contract or modifies that product? Also, your manufacturer should approve your contract with the hospital. If your contract with the hospital provides that you sell a given number of disposables at a certain price, you should have, in writing, an agreement with your principal that it will provide that many disposables at a set price during the pendency of your agreement with the hospital. Otherwise, you could be facing a substantial lawsuit for something that was completely beyond your control.

Delivery. Is product ordered by the hospital being delivered by you as it is ordered, or is any product consigned to the hospital? If consigned, there should be a provision as to where the risk of loss or damage falls. Once the product is consigned to the hospital, it should be the hospital's responsibility until it is returned in its original package undamaged. There should also be a provision as to under what circumstances the hospital can return consigned inventory, and under what circumstances can you insist on the return of such inventory.

Back Orders. What happens if your principal is backordered on the product you are to provide the hospital? Does the contract have any provisions that would protect you in that situation? One of the things that you might consider is having your principal maintain a substantial inventory and possibly consigning it to you. What liability do you have, if any, to the hospital if you simply cannot provide the product that you have contracted to provide?

Litigation. If there is a dispute between the parties, will that dispute be resolved in court or by arbitration? This is a subject that should be discussed with your attorney if it is open for discussion with the hospital. There are pros and cons to either method of litigation. Also, what types of disputes are to be litigated? Some contracts say that only breaches of the contract are to be arbitrated, leaving

open other issues to be decided in court. Other contracts say that all disputes between the parties will be decided by arbitration. This could create a problem if an injured third party sues both the hospital and the distributor. There should be some provision that, regardless of whether all issues are to be arbitrated, in the event that the parties to the hospital contract are brought into an action in court by a third party, the rights as between the distributor and the hospital can be determined by the court.

Description of Products. In any contract between the distributor and the hospital, the products being sold should be described in detail. You should consider whether you want to include in the description of the products the phrase, “including modifications and upgrades of the products.” If the products are modified, does that allow the price to be changed?

The device for which sets are utilized. In the situation where the distributor is providing a device and contracting to provide the disposables, there are a number of issues. Is the device being sold, is it being leased, or is it being placed at no charge during the term of the contract? If it is placed in the hospital, but not being sold to the hospital, is there some time or certain circumstances under which the hospital acquires or can acquire title to the device? If the device is still owned by the distributor, under what circumstance can the distributor take back the device? Certainly, if the hospital defaults on its obligations under the agreement to provide disposables, the distributor should have the right to repossess the device. Also, when the device is in the hospital, who is responsible to insure it, and what limits of liability are to be carried? In that situation, who operates the equipment, what training is given on the equipment, what is the obligation to repair the equipment, and who pays the freight and taxes, if any, and the set-up costs to place the device in the hospital? There may be situations where the distributor does not provide the device, only the disposables. In that case, the contract should make it clear that you are not responsible to maintain or insure the device unless, of course, you are being paid to maintain it.

Rights of Assignment. Can the distributor’s rights under

the contract with the hospital be assigned to another distributor or to the distributor’s principal at the distributor’s request? If the hospital is sold or merged into another entity, can or must the contract be assigned to the new owner?

Recalls. Any contract with the hospital should make a provision for the possibility of recalls and outline a procedure to be followed by both parties in the event of a recall. Does the distributor face any possible liability because of the recall or is liability limited to third-party claims of a defective product? It may be possible to include in the contract that the distributor’s only liability to the hospital, in the event of a recall, is the cost of the devices that are being recalled.

Compliance with Law and Regulations. Any contract between a distributor and a hospital should provide that both parties must abide by all laws and regulations governing the sale and utilization of the product. There probably should be a listing of at least the important laws that must be followed. Many of them are listed in the IMDA form distributor selling agreement. Key laws are the Stark Act and the anti-kickback provisions of the Social Security Act.

Confidentiality. There should be a provision in the agreement that the terms and conditions of the agreement, including price, are to be confidential. You certainly do not want the hospital broadcasting the pricing or terms and conditions of sale or lease that the hospital is being afforded.

Product Warranties. Hospitals will often want you to warrant the condition of the products that you are selling to the hospital. You must be careful to not warrant more than your principal has warranted to you or, if you are in a position that you must warrant more, you should make sure that your insurance covers you.

Insurance Requirements. The contract should provide what insurance each party is to carry, what the amount of each such insurance is to be, and also the fact that the insurance carrier must be a well rated company.

Changes in the Law. The contract should provide that if

the law or regulations dealing with the sale or utilization of the products change, the parties will be bound by those changes or, perhaps, may void the contract.

Choice of Laws. The contract should state what state's laws applies to any disputes between the parties. It may also provide where any litigation or arbitration is to be held. This can be a significant if the distributor is forced to litigate in a location far from its place of business or in a location where the hospital is a major employer. Another provision that is often written into these types of contracts is that the prevailing party is entitled to counsel fees and costs from the other party. This is a very dangerous provision, since even if you feel that you are right, it is risky to litigate any case where you may be responsible not only for your own counsel fees, but if you lose, for the attorneys' fees of the other side.

Addendums and Attachments. Many contracts offered to distributors by a hospital contain addendums and attachments. There is a temptation to read the contract itself carefully, but to ignore any addendums or attachments. Often, these added provisions are as important as or more important than the contract itself. They should be read just as carefully, since, for example, they may contain provisions dealing with liability that do not appear in the body of the contract.

Defects in the Product. There should be a provision in the contract that provides that the hospital has a set limited amount of time to report defects in products shipped to it. Otherwise, it is barred from raising such issues.

AdvaMed Code. Many agreements in the medical device industry, including those between distributors and hospitals, refer to the AdvaMed Code of Conduct and require that that code be followed. The distributor should be familiar with the AdvaMed Code. The IMDA Code of Conduct parallels the AdvaMed Code in many respects, but is more pegged to the ethical requirements of a distributor, whereas the AdvaMed Code is more attuned to the ethical obligations of a manufacturer. If the contract refers to the AdvaMed Code, the contract should be required to have a copy of that code attached as an exhibit. It should be noted that the AdvaMed Code

is sometimes modified, so that a contract should require the distributor and the hospital to abide by that draft of the code that is attached to the contract.

Non-Contractual Protection. When entering into contracts with healthcare providers, be very careful the contract contains the correct names of all of the parties to the contract. Also, look carefully to see whether, if your company is a corporation, you are being asked to sign personal guarantees. If only your corporation is signing the contract, your corporation has limited assets, and you have followed all requirements for maintaining a corporation in good standing (such as annual meetings of shareholders and directors which are memorialized in writing, paying all corporate taxes and franchise fees), you can preserve your own personal assets despite a serious problem involving the corporation. The fact is that no distributor of sophisticated medical devices should operate its business as a sole proprietorship or a partnership. The business should be in an s or c corporation, a limited liability corporation, or some other entity allowed by your state that insulates you from personal liability.

Obligation of Hospital. Particularly in contracts presented to you by healthcare providers, there are generally few obligations imposed on the entity that drafted the contract. You should carefully consider what you need or want the hospital to do, and if it is not already in the contract, which it probably is not, you should negotiate to have it included. For example, the hospital will undoubtedly have a provision requiring you to abide by all laws and regulations. You should insist that the same obligations be placed on the hospital. While everyone must abide by the law, failure to do so is not a breach of contract unless the contract itself requires it. You may want the hospital to have a limited amount of time to reject product. That should be in the contract. The institution should be obligated to return consigned inventory upon your request. If you have to service, repair or install products, there should be a provision that the hospital will afford you reasonable cooperation and assistance.

Penalties for Default. One of the things to look for in any contract is what happens in the event of a default.

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The most usual provision states that the contract can be terminated by the non-defaulting party if a party defaults. Some contracts provide for liquidated damages (that is, a definite dollar amount or formula amount to be paid if there is a breach). You should be aware of the consequences specified in the contract for breach. In contracts with hospitals, you should be particularly alert to a provision that provides that in the event a distributor breaches, it can be debarred from the hospital. While it is bad enough to be unable to sell to one of your potential customers, the consequences of debarment may be much greater. Many contracts between distributors of sophisticated medical devices and the manufacturers of the medical devices provide that the contract may be terminated if the distributor is debarred.

Boiler Plate. The words “boiler plate” or “standard language” are thought by many non-lawyers to mean provisions in contracts that are always used and therefore unimportant. That is a false assumption. Particularly in contracts between distributors and hospitals, many of which have been written for the first time only recently, every provision has to be looked at carefully. If you are told a contract is all boiler plate it may be time to count your fingers.

The language of these types of contracts can greatly affect your bottom line. Your risk of being enmeshed in a long, time-consuming, extremely expensive liability case may depend on the language of the contract. Depending on the language of these contracts you may be putting yourself at risk without even receiving any assurance of your receiving sales orders.

Because of the laws governing the relationship between distributors and hospitals, such as the anti-kickback provisions of the Social Security Act and the Stark Act, these contracts should be very clear on what cannot be done by the distributor in relation to the hospital, its employees and staff physicians or physicians with staff privileges.

If you have made a business decision that you should enter into an agreement with a particular hospital and your bargaining provision is relatively weak, at least know and understand the risks that you are assuming. To the extent that you can ensure against those risks, either through insurance or through careful note taking and recordkeeping in your business, make sure that you protect yourself as well as you can.

Contracts with hospitals are becoming more and more prevalent in the medical industry. The constantly changing nature of the business and the changes in the law and regulations, mean that such contracts will become more prevalent. Whether you are providing product on a long term fixed price contract or the hospital is requiring you to sign an agreement as a condition of your selling any products, there will be more such contracts for you to consider.

In the case of contracts offered to you by hospitals, it is easy to say that there is really nothing you can do and, therefore, just sign whatever is offered. The only thing that can be said as to that type of thinking is “let the seller beware.”