



Facing Legal Issues in the Health Care Industry

By Attorney David P. Mierswa

One of the “hot button” issues facing the healthcare industry is data breaches. As providers switch from paper to complete electronic systems, they face the ever increasing issues of:

- Data breaches
- Compliance with state
- Federal protective and privacy laws.

In 2011, Health and Human Services (“HHS”) levied a fine of \$4.3 million against Maryland based Cignet Health in violation HIPAA. There should be contract terms in place dealing with unauthorized access to private health care data. Providers are facing lawsuits from the government agencies, patients, and other business entities.

Other “hot button” issues include:

- Physician/hospital relationship and violation of “Stark Law”
- Tax exempt status of medical providers
- Co-management and anti-trust issues
- Mergers and anti-trust law
- Labor disputes
- Medical malpractice
- and tort reform

This is a small sample of what medical providers face. To deal with all of the aforesaid issues you need health care contracts that include the following but not limited to:

- Non-disclosure agreement
- Employee contracts
- Physician agreements
- Relocation Agreement
- Partnership agreements
- Purchase and sale contracts
- and other contracts

You are legally as strong as your contracts!

The first rule in dealing in contracts is using a properly qualified and experienced attorney. The second rule is always get in writing!! The following are important contract terms or kinds of contracts you should implement, use, and update. The following is a checklist of the most important provisions to examine, understand, and consider negotiating when entering into a contract with a hospital or other healthcare provider.

Some of the contracts include:

Non-disclosure agreements. Non-disclosure agreements allow a medical provider to protect critical information, systems, client info., and other important information from misuse or theft by third parties. If the third party violates the non-disclosure agreement, the non-breaching party can seek immediate legal injunction to stop any violation and seek other legal remedies, such as attorney fees and legal damages for the breach.

Employee contracts. If you have any employees, you should have them sign a written contract that spells out the terms of their employment. This protects you and the employee. If the conditions of the employer/employee contract are violated, you can take certain defined steps against the breaching party. Also, an employer/employee contract should have the legal remedies and equitable remedies in favor of the non-breaching party.

Physician agreements. If you are a medical provider, you should have a separate written agreement with the physicians that you are employing. This contract is very important because of the fact that you are dealing with doctors and physicians that have certain restrictions and ethical considerations that they have to abide by. Also, there is a high risk that whatever organization the physicians are employed for, of being sued by third parties and patients on a number of legal issues.

Relocation Agreements. If you have highly valued employees and several business units throughout the country, you should have relocation agreements drafted and ready to be used. This is particularly true with health care management and administration employees. The relocation agreement will define the exact terms and liability of the employer and employee. This helps stay lawsuits if there are any complications before, during, and after the relocation.

Partnership agreements. When you are going into business with a third party, you must have a partnership agreement. This agreement is important:

- It defines the terms of the partnership relationship
- Deals with costs
- Profits and/or losses, etc.

If you do not have a partnership contract, most states have a “partnership act.” The terms of the act apply in the absence of a partnership agreement or terms therein. The partnership act might not be favorable terms to your liking.



Purchase and sale contracts. A lot of medical providers have a multitude of locations. The use of purchase and sales agreements are very important when you are purchasing an existing business or a book of clients. The purchase and sales agreement should deal with all aspect of the P and S including the business assets, liabilities, existing patients, real estate, etc.

Other contract terms include the but not limited to the following:

Description of Product and Price. What are you selling or being allowed to sell, and at what price? In any contract between the distributor and the hospital, the products being sold and the pricing 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.

Payment Terms and Effect of Reimbursement. What is the hospital’s obligation if its reimbursement by third-party providers for the product you are selling changes? Is product price somehow tied to reimbursement? Related, is your payment tied to the timing of the hospital’s reimbursement? You should ensure that you understand the timing of payment and negotiate appropriate terms.

Exclusivity. 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? Is your contract with the hospital exclusive or does it allow the hospital to purchase product from other sources?

Length of Contract. What is the contract term? Does it automatically renew or does it expire after a certain time, requiring that that contract be re-negotiated and re-executed? What happens to the price if the contract is renewed? Watch out for contracts that say that they are for a term of a year or years, but include a provision that says that the hospital may terminate the contract with or without cause with a specified amount of notice, frequently 30 days.

Indemnification. One of the major issues in any contract between a hospital and a distributor is who bears financial responsibility in the event of a third-party claim for negligence or product liability. Naturally, there should be insurance. But the agreement must spell out who has to carry insurance, how much insurance must be carried, and whether a party is required to make the other an additional insured on applicable policies.

Product Delivery and Consignment. Does the agreement provide for just-in-time delivery or is product consigned to the hospital? If product is consigned, there should be a provision as to where the risk of loss or damage falls.

Capital Equipment and Disposables. In the situation where the distributor is providing a piece of capital equipment and selling disposables, the contract should provide for the terms under which the equipment is being provided -- i.e., is it being sold, leased, or simply placed in the hospital? Additional issues that may be addressed in the contract are, what training is given on the equipment, who is responsible for the cost of

repairs, and who pays the freight, taxes, and set-up costs to place equipment in the hospital.

Rights of Assignment. Can the distributor’s rights under the contract with the hospital be assigned to another distributor or to a manufacturer at the distributor’s request? If the hospital is sold or merged into another entity, what effect does that have on your rights?

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.

Confidentiality. You may wish to require a contract provision that the terms and conditions of the agreement, including price, are to be confidential.

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 manufacturer has warranted to you. Consider communicating with the manufacturers concerning the scope of warranties and to ensure that you are adequately insured.

Litigation, Choice of Law, and Venue. The contract will probably state what state’s laws applies to any disputes between the parties and provide where any litigation is to be held. It may also provide that any dispute must be resolved in arbitration (rather than a court). You will want to consult a lawyer to determine the meaning and effect of these provisions. 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.

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 the addendum, addendums or the attachment.

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

Compliance with Law and Regulations. Any contract between a distributor and a hospital should provide that all 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.

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.

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. As referenced above, understand whether you are being asked to provide a personal guarantee. If only your corporation is signing the contracts, and you have followed all requirements for maintaining a corporation in good standing (such as conducting annual meetings of shareholders and directors, keeping current on required filings, and paying all corporate taxes and franchise fees), you can usually protect your personal assets in the event of a lawsuit.

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

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 carefully examined. 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.

When facing the endless legal issues in the health care industry, your solution is developing a team to deal with those risks. Part of your team is having a highly experienced law firm draft contracts that minimize the legal risk. The Law Offices of David P. Mierswa and Associates, PC have been drafting contracts for 16 plus years. Contact Attorney David P. Mierswa for further information or to have any questions answered.

