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HEALTH CARE

Supply Chain Desk Reference

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The health care industry is a heavily regulated industry with many regulations applicable to the manufacture and sale of medical devices, supplies, equipment, products, and pharmaceuticals. Both manufactures and customers operating in the health care space need to be aware of and comply with various regulations when contracting for medical products.

This is a high-level summary of certain of the common issues for consideration and regulations affecting health care supply chain management and the contracting process.

I. FRAUD AND ABUSE

A. Anti-Kickback Statute

1. What are Anti-Kickback Statutes?

The federal Anti-Kickback Statute ("AKS"), as well as state anti-kickback laws, may apply to relationships between individuals and entities within the supply chain as well as to those entities' relationships with health care providers. It is imperative to determine whether federal and/or state anti-kickback laws apply to a supply chain relationship or arrangement.

The federal AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients). *See* 42 U.S.C. § 1320a-7b. The AKS has a broad reach and covers both medical product manufactures, sellers and distributors, in addition to health care customers. The AKS covers the payers of kickbacks (i.e. those who offer or pay remuneration) as well as the recipients of kickbacks (i.e. those who solicit or receive remuneration). Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs.

2. AKS Safe Harbors.

In health care, a "safe harbor" is a recognized exception to the AKS. While the AKS prohibits financial relationships between referral sources and business partners in general, safe harbors offer avenues to structure the exchange of remuneration in a legal fashion in that they immunize certain payment and business practices that are implicated by the AKS from criminal and civil prosecution under the statute. To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor. Failure to comply with a safe harbor provision does not mean that an arrangement is *per se* illegal. Compliance with safe harbors is voluntary, and arrangements that do not comply with a safe harbor must be analyzed on a case-by-case basis for compliance with the AKS.

The Office of Inspector General ("OIG") has issued numerous safe harbors, including the following safe harbors, which safe harbors can be directly applicable to supply chain arrangements: Discounts; Warranties; Equipment Rental; and Group Purchasing Organizations ("GPOs").

a. Discounts Safe Harbor.

i. What is the Discount Safe Harbor?

Under the Discount safe harbor (42 C.F.R. § 1001.952(h)), "remuneration" does not include a ***discount*** on an item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs so long as each

of the buyer and the seller/offeror complies with certain standards. There are different standards depending upon the entity type. For example, there are standards that are applicable to buyers that is a health maintenance organization or a competitive medical plan, and then standards applicable to a buyer that is an entity that reports its costs on a cost report form.

For purposes of the safe harbor, the term *discount* means a reduction in the amount a buyer is charged for an item or service based on an arms-length transaction.

ii. What Does a Discount Not Include?
However, a *discount* does not include things such as:

(i) cash payment or cash equivalents;

(ii) supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, *unless* the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) a reduction in price applicable to one payer but not to Medicare, Medicaid, or other Federal health care programs;

(iv) a routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) warranties (which is a separate category of Safe Habor as described in Section 2 below)

iii. Buyer Compliance with the Discount Safe Harbor.
In general, with respect to buyers, to be compliant with the Discount safe harbor:

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) The buyer must provide, upon governmental request, information provided by the seller/offeror as specified in the safe harbor.

iv. Seller Compliance with the Discount Safe Harbor.
In general, with respect to sellers/offerors, to be compliant with the Discount safe harbor, and where the buyer is an entity that reports its costs on a cost report form:

(A) Where the value of the discount is known at the time of sale, the seller must:

(i) fully and accurately report any discount given on the invoice, coupon or statement submitted to the buyer;

(ii) inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request; and

(iii) refrain from doing anything that would impede the buyer from meeting its obligations under the safe harbor; or

(B) Where the value of the discount is not known at the time of *sale (as in the case rebates), the seller must:*

(i) fully and accurately report the existence of a discount program on the invoice, coupon, or statement submitted to the buyer;

(ii) inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request;

(iii) when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and

(iv) refrain from doing anything which would impede the buyer from meeting its obligations under the safe harbor.

For purposes of the Discount safe harbor a *rebate* is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

v. Representative Contract Language.
Health care customers often look for and require warranties addressing compliance with the Discount safe harbor in supply chain contracts. Sample, representative, contract terms include:

The Parties shall comply with the reporting requirements of 42 C.F.R. §1001.952(h), regarding "safe harbor" protection for discounts under the Anti-Kickback Statute. Seller represents and warrants that any discount or rebate provided to Buyer satisfies the requirements of the Anti-Kickback Statute Safe Harbor at 42 C.F.R. §1001.952(h); in no event shall Seller offer or provide any discounts or rebates that involve the impermissible bundling of products or involve multiple products where such products are not reimbursable under the same Federal Health Care Program using the same methodology. Seller warrants that, if a rebate or discount involves multiple products, that all of the products provided are reimbursable under the same Federal Health Care Program using the same methodology. Seller shall disclose to Buyer on each invoice, or as otherwise agreed in writing, the amount of any discount or rebate relating to the products sold hereunder. The statement shall inform Buyer in a clear and simple manner of the amount of the discount or rebate so as to enable Buyer to fully satisfy its obligations to report such discount or rebate to Medicare.

b. Warranties Safe Harbor.

Under the Warranties safe harbor (42 C.F.R. § 1001.952(g)), "remuneration" does not include any payment or exchange of anything of value under a ***warranty*** provided by a manufacturer or supplier (provided the warranty covers at least one item) to the buyer of the items and services, as long as each of the manufacturer/supplier and the buyer complies with certain standards.

The term ***warranty*** means:

(i) Any written affirmation of fact or written promise made in connection with the sale of an item or bundle of items, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, which affirmation of fact or written promise relates to the nature of the quality of workmanship and affirms or promises that such quality or workmanship is defect free or will meet a specified level of performance over a specified period of time;

(ii) Any undertaking in writing in connection with the sale by a manufacturer or supplier of an item or bundle of items, or services in combination with one or more related items, to refund, repair, replace, or take other remedial action with respect to such item or bundle of items in the event that such item or bundle of items, or services in combination with one or more related items, fails to meet the specifications set forth in the undertaking which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a seller and a buyer for purposes other than resell of such item or bundle of items; or

(iii) A manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item or bundle of items (which is covered by an agreement made in accordance with the terms herein), on terms equal to the agreement that it replaces.

i. Buyer Compliance with Warranties Safe Harbor.

In general, with respect to buyers, to be compliant with the Warranties safe harbor:

(i) the buyer (unless the buyer is a Federal health care program beneficiary) must fully and accurately report any price reduction of an item or service (including a free item or service) that was obtained as part of the warranty in the applicable cost reporting mechanism or claim for payment; and

(ii) the buyer must provide, upon governmental request, information provided by the manufacturer or supplier regarding the warranty.

ii. Seller Compliance with Warranties Safe Harbor.

With respect to manufacturers/suppliers, to be compliant with the Warranties safe harbor:

(a) The manufacturer or supplier must comply with either of the following standards:

(i) The manufacturer or supplier must fully and accurately report any price reduction of an item or service (including free items and services) that the buyer obtained as part of the warranty on the invoice or statement submitted to the buyer and inform the buyer of its obligations under the safe harbor.

(ii) When the amount of any price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under the safe harbor, and when any price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(b) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

(c) If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment.

(d) The manufacturer or supplier must not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services.

iii. FDA-Related Product Warranties.

It should be noted that when the supply chain contract involves the sale of products regulated by the FDA, health care entity customers normally seek warranties from the manufacturer that go beyond warranties given in the product's labeling, and which address certain health care regulations. For example, a health care entity may seek warranties that the products:

(a) will be and shall remain in compliance with, all applicable federal, state and local laws, regulations, ordinances, regulations and codes, including, but not limited to:

(i) those relating to the privacy or security of information including, but not limited to, HIPAA and corresponding regulations; and

(ii) CMS regulation; and

(b) have received FDA approval or will have 510K clearance prior to delivery to Customer and will be in compliance with FDA regulations.

c. Equipment Rental Safe Harbor.

Under the Equipment Rental safe harbor (42 C.F.R. § 1001.952(c)), "remuneration" does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met:

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time

basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or all other Federal health care programs.

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

Note that, the term *fair market value* means that the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

d. GPO Safe Harbor.

Under the GPO safe harbor (42 C.F.R. § 1001.952(j)), "remuneration" does not include any payment by a vendor of goods or services to a GPO, as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met:

(a) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following:

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(b) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

The term *group purchasing organization* means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health

care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

GPOs, and their health care members, will often require any vendor/supplier agreements be structured to comply with the applicable AKS safe harbors discussed above. Vendors/suppliers, when contracting with GPOs have a need to ensure that the entity meets the definition of a GPO above, otherwise any fees to be paid to the GPO may not be afforded safe harbor protection.

B. Stark Law

1. What is the Stark Law?

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" (or "DHS") payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception (safe harbor) applies. *See* 42 U.S.C. § 1395nn. Financial relationships include both ownership/investment interests and compensation arrangements. The Stark law is a strict liability statute and thus, no proof of bad intent is required to violate the Stark law. The Stark law provides for significant civil sanctions for violations including, but not limited to: the denial of payment of a claim; refunds of amounts collected in violation of the statute; and civil monetary penalties ("CMPs") up to $15,000 for each claim submitted in violation of the statute.

With respect to supply chain arrangements, the Stark law may be implicated if and when a manufacturer/supplier is owned by one or more providers or physicians and/or if physicians or providers have investment interests in the manufacturer/supplier, and in the case of the foregoing where any such ownership or investment interest would cause this arrangement to create a financial relationship between a "DHS entity" and a physician (hereinafter a "Stark Entity").

2. Stark Law Safe Harbors.

Supply chain arrangements between a health care customer and a seller that is a Stark Entity, in addition to being structured to comply with the AKS and its applicable safe harbors, should be structured to comply with one or more of the safe harbors to the Stark law. Stark law safe harbors that are often relied upon, and which can be applicable to supply chain arrangements include:

a. **Equipment Rental Safe Harbor (42 C.F.R § 411.357 (b)).** This safe harbor allows for the rental of equipment, provided the lease and arrangement meets certain standards such as a lease term of not less than one (1) year, exclusive use of the equipment during the lease term, and rent being commercially reasonable, consistent with fair market value, and not being determined in a manner that takes into consideration the volume or value of referrals or including per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

b. **Fair Market Value Compensation Safe Harbor (42 C.F.R § 411.357 (l)).** This safe harbor protects compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians for the provision of items or services or for the lease of office space or equipment by

the physician, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets certain conditions. Such conditions include requirements that the compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Notably compensation for the equipment may not be determined using a formula based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

c. **Timeshare Arrangements (42 C.F.R § 411.357 (y)).** This safe harbor protects an arrangement for the use of premises, equipment, personnel, items, supplies, or services if certain conditions are met. Included in the compliance requirements are that the premises, equipment, personnel, items, supplies, and services covered by the arrangement are used predominantly for the provision of evaluation and management services to patients; and on the same schedule. Specifically with respect to equipment, the equipment must be located in the same building where the evaluation and management services are furnished; not be used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and not be advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests). As with the equipment rental safe harbor, the compensation must be set in advance, commercially reasonable, consistent with fair market value, and not determined:

    (i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

    (ii) Using a formula based on:

        (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

        (B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

II. REGULATORY COMPLIANCE

Vendors entering into supply chain arrangements with health care entities may also be required to, depending upon the nature of the product or service, make attestations of compliance with, and /or comply with various regulations to which the health care entity is subject. The applicability of such regulations to the supply chain arrangement and the parties thereto should be evaluated on a case by case basis. Below is a non-exhaustive listing of certain regulations that may be applicable to the supply chain arrangement and which are typically addressed in supply chain arrangements with health care entities.

A. Excluded Entities/Individuals.

The OIG has the authority to exclude individuals and entities from Federally funded health care programs for a variety of reasons, including a conviction for Medicare or Medicaid fraud. OIG imposes exclusions under the authority of sections 1128 and 1156 of the Social Security Act ("Act"). Those that are excluded can receive no payment from Federal health care programs for any items or services they furnish, order, or prescribe.

Notably, if a healthcare provider arranges or contracts with an excluded individual or entity for the provision of products or services reimbursable under such a Federal program, the health care provider may be subject to CMP liability. For liability to be imposed, the provider submitting the claims for health care products or services furnished by an excluded individual or entity "knows or should know" that the person was excluded from participation in the Federal health care programs *(See section 1128A(a)(6) of the Act; 42 CFR 1003.102(a)(2)).*

4. Representative Language.

Due to the above "knowledge" requirement, health care providers often require that vendors provide a warranty of non-exclusion in supply chain contracts, with such warranty tracking the OIG exclusion authority and screening recommendations. Sample contract language is as follows:

> Supplier represents and warrants that neither it nor any of its employees, directors, officers, equity owners, personnel, subcontractors or agents under this Agreement (collectively, "Supplier Personnel") are excluded from participation, or are otherwise ineligible to participate, in a "federal health care program" (as defined in 42 USC §1320a-7b(f)) or in any other government payment program, and that no such action is pending. Supplier will assess the status of the Supplier Personnel prior to hire or contracting and on a monthly basis thereafter as required by the United States Department of Health and Human Licensed Services ("DHHS") or the Centers for Medicare and Medicaid Licensed Services ("CMS"). Supplier will notify Customer in writing within _____ (__) days of either of the following: (a) the discovery of any debarment, exclusion, suspension or other event that makes Supplier or any Supplier Personnel ineligible to participate in a federal health care program or any other government payment program; or (b) any conviction of Supplier or any of the Supplier Personnel of a criminal offense that falls within the scope of 42 USC §1320a-7(a), even if they have not yet been excluded, debarred, suspended or otherwise declared ineligible. If Supplier is in breach of this Section or upon the occurrence of such exclusion,

debarment, suspension or conviction of Supplier or any Supplier Personnel, whether or not notice is given, Customer may immediately terminate this Agreement.

B. HIPAA.

1. Protected/Personal Health Information (PHI).

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge. The DHHS issued the HIPAA Privacy Rule to implement the requirements of HIPAA, and the HIPAA Security Rule protects a subset of information covered by the Privacy Rule. The Privacy Rule standards address the use and disclosure of individuals' protected/personal health information ("PHI") by organizations subject to the Privacy Rule ("covered entities"), as well as standards for individuals' privacy rights to understand and control how their health information is used. The Security Rule established a national set of security standards for protecting PHI that is held or transferred in electronic form, and operationalizes the protections contained in the Privacy Rule by addressing the technical and non-technical safeguards that covered entities must put in place to secure individuals' electronic PHI ("e-PHI").

2. Business Associate Agreements

Covered entities are permitted under HIPAA to disclose PHI and e-PHI to a business associate ("BA"), who is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. Covered entities are required to enter into business associate agreements ("BAAs") with such BAs. Per regulation, a BAA is required to contain certain elements, including provisions describing the permitted and required uses of PHI by the BA; providing that the BA will not use or further disclose PHI other than as permitted or required by the contract or as required by law; and requiring the BA to use appropriate safeguards to prevent a use or disclosure of the PHI. (*See* 45 CFR 164.504(e)).

Whether or not a supply chain arrangement necessitates a BAA is generally determined on a case by case basis. For example, consideration may given as to whether PHI is involved with the transaction and whether the vendor will have potential access or exposure to PHI or if the arrangement will involve electronic transmission of PHI to sources outside the customer's systems. Examples of products that may involve HIPAA include but are not limited to: equipment such as a scanner, fax machine, copier, medical equipment, etc. Consider that the memory in the machine may cache or store images or data containing PHI; or software that includes remote access to, storage or management of data. Most but not all supply chain arrangements involving HIPAA will be related to purchasing services, and often transactions involving software access and usage.

3. Representative Language.

While it is common for health care customers to add provisions addressing HIPAA compliance and applicability in their supply chain contracts (see below for sample language), many health care entities require vendors and sales representatives, as part of the entity's vendor credentialing process, to execute BAAs as a matter of practice. Execution of a BAA is sometimes built into the automatic, electronic vendor credentialing that is a requirement of entry into the health care provider's facilities.

The Parties shall, as applicable to each comply with the Health Insurance and Portability and Accountability Act of 1996 (P.L. 104-191), 42 U.S.C. §1320d, et seq., and the regulations promulgated there under ("HIPAA"). Supplier affirms that its provision of the products (and any related services hereunder) hereunder does not require possession or use of, or access to, any Protected Health Information ("PHI") or Electronic Protected Health Information ("ePHI"), each as defined by HIPAA. Supplier agrees that if the nature of this arrangement changes, so that Supplier qualifies as a business associate under HIPAA, the Parties shall seek to negotiate and execute a business associate agreement that complies with HIPAA.

C. FDA Recall.

1. Types of Recalls.

A recall is (a) a manufacturer's removal or correction of a marketed product that the FDA considers to be in violation of the Food Drug & Cosmetic Act ("FDCA") and against which FDA would initiate legal action, or (b) voluntary action taken by a manufacturer when it determines a device is misbranded or adulterated under the FDCA.

Recalls may be conducted on a manufacturer's own initiative (*See* 21 C.F.R. 7), by FDA request, or by FDA order under statutory authority. For example, FDA regulations set forth specific requirements for mandatory recalls of devices/products subject to supply chain transactions such as medical device corrections and removals (21 C.F.R part 806), mandatory device recalls (21 CFR 810), electronic product notifications and corrections (21 C.F.R parts 1003 and 1004) and mandatory recalls for human cells, tissues, and cellular and tissue-based products (subpart F of 21 C.F.R 1271).

- **Class I Recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II Recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III Recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- **Market Withdrawal:** occurs when a product has a minor violation that would not be subject to FDA legal action. The manufacturer removes the product from the market or corrects the violation.
- **Medical Device Safety Alert:** issued in situations where a medical device may present an unreasonable risk of substantial harm. In some case, these situations also are considered recalls.

2. Recall Reporting.

The FDA's Center for Devices and Radiological Health requires manufacturers to follow 21 CFR Part 806 for reporting medical device recalls. Reporting includes, but is not limited to, information on corrective or removal actions that have been, and are expected to be taken as well as of copies of communications regarding the correction or removal, including name and contact information of all recipients of the communications.

3. Representative Language.

Supply chain arrangements involving medical devices and products will often contain contractual terms addressing the role of each party, the supplier and customer, in the event of a recall. The contractual language normally include notice provisions (including timing depending upon the type of recall), instructions as to actions to be taken, as well as financial terms.

> Supplier shall immediately provide Customer with a copy of all communications from Supplier and/or the FDA advising of a recall, request for a recall, market withdrawal, or safety alert. Supplier shall provide Customer with written notice of any Class I recall, whether voluntary or initiated by the FDA, affecting any of the products covered hereunder within twenty-four (24) hours of Supplier's receipt of any such request for a recall, or shorter period of time provided in the recall strategy. Supplier shall reimburse Customer for any costs actually incurred by Customer in complying with any recall instructions and processes provided by Supplier.

D. Device Tracking.

Health care entities and manufacturers of medical devices and products each have medical device reporting and tracking requirements.

With respect to health care entities, the Safe Medical Devices Act of 1990 (SMDA) (Public Law 102-629) requires ambulatory surgery centers, hospitals, outpatient diagnostic centers and other user facilities to report all incidents in which a medical device or user error may have caused or contributed to the death, serious injury or serious illness of a patient. To assist in meeting these requirements health care entities often look to manufactures to provide it with certain product information and make the provision of such information a contractual requirement. For example, a contract may require that the manufacture supply the customer with, for all devices/products covered by the contract, the manufacturer's product tracking number and SKU, GLN, UPN, UNSPSC, and GTIN.

Manufacturers are required to track certain devices from their manufacture through the distribution chain when they receive an order from the FDA to implement a tracking system for a certain type of device. The purpose of device tracking is to ensure that manufacturers of certain devices establish tracking systems that will enable them to promptly locate devices in commercial distribution. Tracking information may be used to facilitate notifications and recalls ordered by FDA in the case of serious risks to health presented by the devices.

E. Access to Records.

Per regulations implementing section 952 of the Omnibus Reconciliation Act of 1980 (Pub. L. 96-499), Medicare reimbursement for the cost of services performed under certain contracts is conditioned upon compliance with prescribed criteria. (*See* 42 C.F.R. 420.302). If a contract between a provider and a subcontractor covers services valued at or costing $10,000 or more over a 12-month period, Medicare reimbursement cannot be made for the services unless the contract includes a clause allowing the Secretary of Health and Human Services and the Comptroller General access to the contract and to the subcontractor's books, documents, and records necessary to verify the costs of the contract. This is commonly referred to as an "Access to Records" clause. Additionally, the clause must also permit similar access to any subcontract between the subcontractor and a related organization of the subcontractor when the subcontract is worth or costs $10,000 or more over a 12-month period. These regulations specify the criteria and procedures that the DHHS will use to obtain access to affected books, documents, and records. The purpose of the legislation and these proposed regulations is to permit the Secretary and Comptroller General to make an accurate determination of the reasonable costs under these contracts.

While not all supply chain arrangements will fall under the ambit of the above, it is common for supply chain contracts with health care entities to contain an Access to Records clause that is triggered only if and when applicable. For example:

> To the extent that Section 952 of the Omnibus Reconciliation Act of 1980 (the "Act") and the regulations promulgated thereunder are applicable to this Agreement, Supplier, and any organizations related to it performing any of the duties pursuant to this Agreement valued at Ten Thousand Dollars ($10,000) or more in any twelve (12)-month period shall, until four (4) years after the furnishing of services pursuant to this Agreement, comply with requests of the Comptroller General, the Secretary of the Department of Health and Human Services, and their duly authorized representatives for access (in accordance with Section 952 of the Act) to any contract or agreement between Supplier and Customer for services and to any contract or agreement between Supplier and such related organizations, as well as the books, documents and records of Supplier and its related organizations, if any, which are necessary to verify the cost of the services provided.

BATTLE OF THE FORMS

Natalie Neals and Ryan Riffle

I. What is a "Battle of the Forms"?

A. A "battle of the forms" occurs when a seller and a buyer in a transaction involving tangible goods exchange standard forms. These forms usually contain terms that are in addition to, or are different than, the terms in the other party's form. For example, a buyer submits a purchase order with small-print terms and conditions of purchase printed on the back. In response the seller wants to accept the order but does not want to agree to the fine print, so it sends back an order acknowledgment that includes its standard terms and conditions of sale.

B. This common scenario becomes an issue under Article 2 of the Uniform Commercial Code (the "U.C.C."). Article 2 states that any definite and seasonable expression of acceptance, or a written confirmation, sent within a reasonable time after a sales offer has been sent can constitute acceptance of an offer, even if the two documents contain different terms. U.C.C. § 2-207(1).

C. When the forms contain different terms, the "battle" occurs to determine which terms will control. Terms that conflict are knocked out and replaced with U.C.C. gap-fillers. U.C.C. 2-207(3).

D. Additional terms (new terms in the acceptance that do not contradict a term in the offer) become part of the agreement unless (1) the offer expressly limits acceptance to the terms of the offer; (2) the additional terms materially alter the agreement; or (3) the party making the offer has already given notice of objection to the terms, or objection is given within a reasonable time after notice of them is received.

E. If the acceptance or confirmation is expressly conditional on the agreement of the party that made the offer to the additional or different terms, the acceptance/confirmation is deemed to be a counteroffer, and no written contract is formed. A contract may then be created by the conduct of the parties recognizing that a contract exists (typically delivery of the product by the seller and acceptance thereof by the buyer). The terms of that agreement are any terms on which the forms of the parties agree, plus any "gap-filler" terms from Article 2 of the U.C.C. A court can apply gap-filler terms for everything except the identification of the goods themselves and the quantity. Most of the gap-filler terms are highly buyer-friendly (for example, warranties implied by law into the contract and unlimited damages for breach).

F. Not taking proper consideration of the "battle of the forms" can result in inconsistent results and agreement to onerous terms.

II. Practical Ways to Deal with Battle of the Forms as a Seller.

A. Make sure your standard documents include the "Magic Language."

Failing to include this language could mean that the seller is accepting the properly submitted terms and conditions of the buyer.

EXAMPLE "MAGIC LANGUAGE":

"Offer. This document is an offer or counter-offer by Seller to sell the goods and or services described in it in accordance with these terms and conditions, is not an acceptance of any offer made by buyer, and is expressly conditioned upon buyer's assent to these Terms and Conditions of Sale. Seller objects to any additional or different terms contained in any request for proposal, purchase order, or other communication previously or hereafter provided by buyer to Seller. No such additional or different terms or conditions will be of any force or effect."

B. Always read agreements and forms carefully and make sure that the terms are acceptable before signing or sending back a conflicting standard form. Timely object in writing to any terms that are not acceptable.

C. Do not sign buyers' forms. Encourage buyers to sign your forms. Do not make reference to buyers' forms in any correspondence.

D. In internet sales, require buyers to click to accept your terms of sale in order to be able to place an order.

Common Scenario: Buyer sends seller a purchase order with its terms and conditions. Seller sends back an order acknowledgment with its terms and conditions.

IS THERE A CONTRACT?

If both parties' terms include the "magic language."

Do the parties conduct themselves as if there is a contract?

- NO → No contract
- YES → Yes, there is a contract. Agreed terms stay in. Contradicting terms are out and replaced with gap fillers from the U.C.C.

If the buyer's terms include the "magic language" but the seller's terms do not.

YES

But, seller's additional terms are not made part of the contract.

If the seller's terms have "magic language" but the buyer's terms do not.

If neither parties' terms contain the "magic language"

YES

The order acknowledgment acts as acceptance, even if it has additional or different terms. The additional terms are incorporated unless

(1) the terms materially alter the agreement or

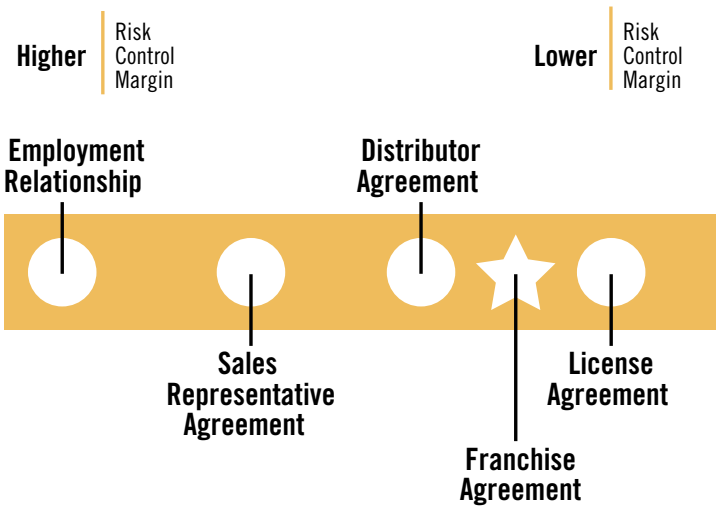
(2) notice of objection of the terms is given within a reasonable time after receipt of the additional terms.

DISTRIBUTION SUPPLY CHAIN OPTIONS

Kate Wegrzyn

When determining how to sell a product in the marketplace, there are a number of supply chain options from which to choose, each with its own set of legal implications. However, the primary consideration in determining how to sell a product should be what makes the most sense from a business perspective (for example, if the product requires, a large physical inventory, having these responsibilities outsourced to a distributor may be the most practical solution).

Here is a high-level summary of the common ways to sell product:



I. Employee (Vertical Integration).

A. Overview. Supplier employs salespeople to sell the product directly to the ultimate customer. The costs associated with this structure are higher, as more resources are needed to implement it. The margin tends to be higher because there is no intermediary.

B. Compensation. The employee is paid a salary (which may be commission-based).

C. Credit Risk. Supplier bears the credit risk as to the ultimate customer (that is, if the ultimate customer does not pay, Supplier is not paid).

D. Control. Supplier retains the relationship with the ultimate customer and has complete control over the sales activities, including pricing.

E. Termination. Termination follows local labor laws. In most states in the United States, the employee may be terminated at will.

II. Sales Representative Agreement.

A. Overview. Supplier contracts with an independent contractor, who solicits orders for the product from the ultimate customer and passes those orders on to Supplier. Supplier is able to accept or reject the orders, and accepted orders are contracts between the Supplier and the ultimate customer.

B. Compensation. Supplier pays a commission to the sales representative, which is often a percentage of the invoice value of the accepted orders that the sales representative solicited and the supplier accepted.

C. Credit Risk. Supplier bears the credit risk as to the ultimate customer. (If it is unclear if the relationship is one of a distributorship or a sales representative, this factor will likely be determinative.)

D. Control. Supplier retains nearly-complete control of the sales activities, including pricing. However, the sales representative may have the personal relationship (but not the legal relationship) with the ultimate customer.

E. Termination. A few jurisdictions have statutory protections against terminating sales representatives, but, in large part, termination is unrestricted by law, provided that the sales representative is paid timely for any outstanding commissions.

III. Distributor Agreement.

A. Overview. Supplier contracts with a distributor, who purchases the product from the Supplier for re-sale in the contractually-prescribed territory. Many states have statutes requiring that the Supplier compensate a distributor for warranty work done by the distributor at statutorily-prescribed rates.

B. Compensation. Distributor resells the product at a markup, with such profit being the distributor's only compensation.

C. Credit Risk. Distributor bears the credit risk as to the ultimate customer. Supplier bears the credit risk as to the distributor.

D. Control. Supplier's control of the sales activities (including pricing) is limited by antitrust and other principles. Further, the distributor maintains the personal and legal relationship with the ultimate customer.

E. Termination. The termination or non-renewal of a distributor is often restricted by statute (particularly in certain industries, like motor vehicles, industrial or construction equipment, and agricultural equipment), and may require the buy-back of inventory or may prohibit any termination without good cause.

IV. Franchise Agreement.

A. Overview. Supplier (called the franchisor) contracts with a franchisee, who (i) purchases product from Supplier for re-sale in the contractually-prescribed territory and/or (ii) operates a local business that, to the outside world, is indistinguishable from Supplier's locations. This model is a hybrid of a distributorship that involves additional statutorily-prescribed factors (which usually include the payment of a franchise fee by the franchisee to the Supplier and a heavy reliance by the franchisee on the trademarks of the Supplier). This model requires the Supplier to furnish franchise disclosures akin to securities offering circulars, and registration in certain states.

A. Compensation. Franchisee resells the product at a markup, with such profit being the franchisee's only compensation.

B. Credit Risk. Franchisee bears the credit risk as to the ultimate customer. Supplier bears the credit risk as to the franchisee.

C. Control. Supplier's control of the sales activities (including pricing) is limited by antitrust and other principles. The franchisee maintains the relationship with the ultimate customer, although, as a practical matter, the goodwill generated by the franchisee's activities accrues primarily to Supplier. Supplier must also exercise quality control over the franchisee's operations.

D. Termination. The termination or non-renewal of a franchise is heavily regulated, making termination difficult in many states unless the Supplier has good cause.

V. License Agreement.

A. Overview. Supplier (called the licensor) contracts with a licensee, who licenses Supplier's intellectual property and technology in order to manufacture and sell the product.

B. Compensation. Licensee receives the revenue generated from the sales of the licensed product, while Supplier receives a royalty, typically based on the revenue generated from the licensee's sales of licensed products.

C. Credit Risk. The licensee bears the credit risk as to the ultimate customer. The Supplier bears the credit risk as to the licensee.

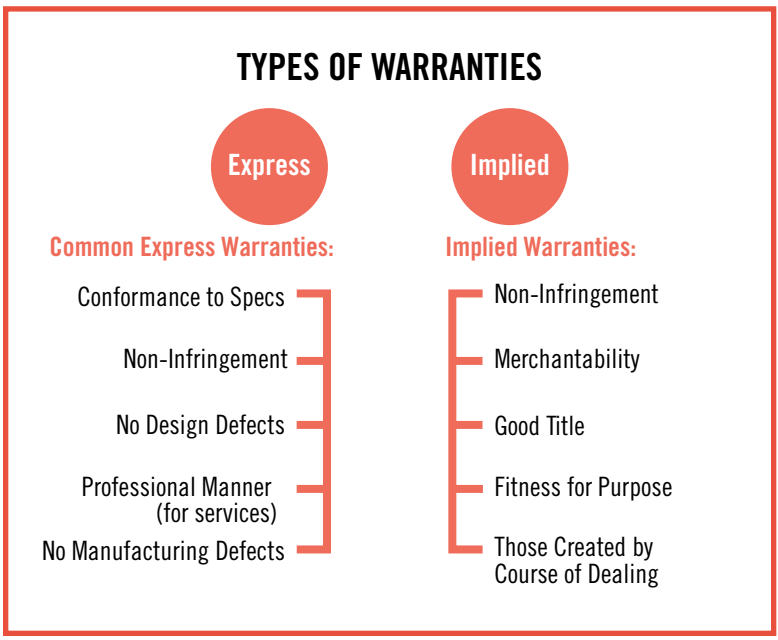
D. Control. Supplier typically has very little control over the licensee's sales activities and maintains no relationship with the ultimate customer.

E. Termination. Unless the licensing relationship also satisfies the elements of a franchise, then issues surrounding term/termination are purely a matter of contract.

WARRANTIES

Rich Casper and Kate Wegrzyn

Warranties are of two types: express warranties and implied warranties.



I. Implied Warranties

Sections 2-314 and 2-315 of the U.C.C. impose on sellers of goods broad implied warranties of merchantability and fitness for particular purpose, and provide for the possibility of other, implied warranties arising from course of dealing or usage of trade (in addition to the warranties of title and freedom from infringement found in U.C.C. § 2-312).

The distinction between contracts for the sale of goods and contracts for services is not always clear. Most courts that have addressed that distinction in the context of contracts requiring the supplier to provide both goods and services have adopted the principle that, if the "predominant purpose" of the contract is a sale of goods, then the contract will be covered by U.C.C. Article 2, and otherwise it will not be. In the latter case, more fluid common law principles will dictate whether the customer is entitled to any implied warranties, and what those are.

A. Implied Warranty of Merchantability. There is an implied warranty of merchantability in each sale of goods contract, unless excluded or modified. In order to be merchantable, goods must at least:

- Pass without objection in the trade under the contract description;
- Be of fair average quality within the description (for fungible goods);
- Be fit for the ordinary purposes for which such goods are used;
- Run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved;
- Be adequately contained, packaged, and labeled as the agreement may require; and

- Conform to the promise or affirmations of fact made on the container or label, if any. U.C.C. § 2-314(2).

B. Implied Warranty of Fitness for a Particular Purpose. Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is, unless excluded or modified under U.C.C. § 2-316, an implied warranty that the goods shall be fit for such purpose. U.C.C. § 2-315.

C. Course of Dealing or Usage of Trade. Other implied warranties may arise from course of dealing or usage of trade (unless excluded or modified). U.C.C. § 2-314(3).

D. Disclaimer of Implied Warranties. As adopted in many states, the U.C.C. permits the implied warranties as to product quality to be disclaimed. The primary requirements for an effective disclaimer are: (1) notice of the disclaimer before purchase, and (2) use of **CONSPICUOUS** type. For the disclaimer of the warranty of merchantability, the disclaimer must also mention merchantability to be sufficient. A phrase that the goods are being sold "**AS IS**" is also sufficient to disclaim implied warranties. U.C.C. § 2-316.

II. Express Warranties

Express warranties are created by (a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods, (b) any description of the goods, and (c) any sample or model, in each case which is made part of the basis of the bargain. It is not necessary that the seller use formal words such as "warrant" or "guarantee" or that the seller have a specific intention to make a warranty. U.C.C. § 2-313.

III. Warranty Remedies

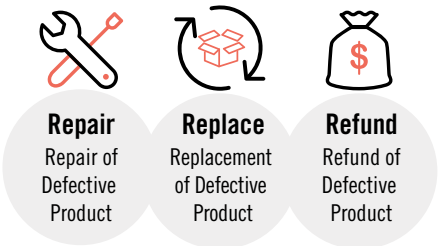
A. U.C.C. Remedies. The "warrantor" (the person giving the warranty) is responsible to the buyer for all losses that can be shown to have resulted from the breach (see U.C.C. §§ 2-714 and 2-715).

B. Limitation on Remedies. Remedies can be limited, but

1. Damages for personal injury caused by a consumer product cannot be limited (U.C.C. § 2-719(3)),
2. The remaining remedy must fulfill its "essential purpose", which is generally considered to mean that the buyer must get something commensurate with the product it bought (U.C.C. § 2-719(2)), and
3. The disclaimer must be **CONSPICUOUS** and carefully drafted.

C. Sole and Exclusive Remedies. Warranty remedies in supply agreements are typically limited to repair or replacement of the non-conforming products or reimbursement of the purchase price paid by the buyer for the non-conforming products. From the Seller's perspective, the foregoing remedies should typically be expressly provided to be the sole and exclusive remedies available to the buyer for a breach of the warranties set forth in the supply agreement. U.C.C. § 2-719(1)(b).

REMEDIES
Warranty remedies are typically limited to



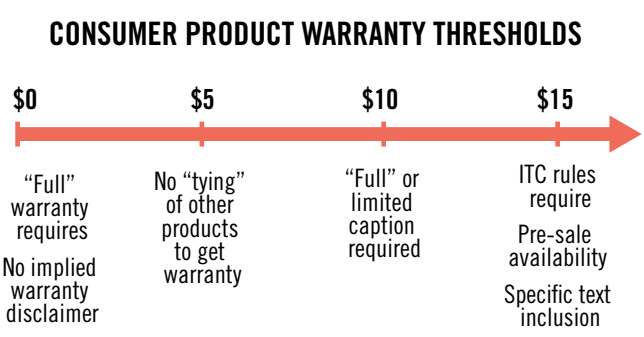
IV. Consumer Warranties

There are additional warranty laws and regulations in place to protect consumers when a warranty is given. The below is a brief overview of such laws and regulations:

A. Federal Law Regulating Written Consumer Warranties (15 U.S.C. § 2301 (2018) et seq., the "Magnuson-Moss Warranty Act").

1. The statute applies only to **written warranties** and only when the products warranted are purchased for personal, family or household use. Sellers are not required to furnish written warranties.
2. Provisions affecting warranties on **all products:** If the warrantor designates a warranty as "full", the warranty must include certain minimum protections. Implied warranties may not be entirely disclaimed; at most, they may be limited to the duration of the written, express warranty.
3. Additional provision affecting warranties on **products costing more than $5:** the warrantor may not require the consumer, in order to get warranty service, to pay for anything identified by a brand name.
4. Additional provision affecting warranties on **products costing more than $10:** the warranty caption must include either the word "full" or the word "limited."
5. The statute may be enforced by the Federal Trade Commission (or the U.S. Department of Justice), state attorneys general and consumers (including class actions), and permits a court to award attorneys' fees to a successful plaintiff. Remedies are damages and injunctions.

B. FTC Rules Regulating Written Consumer Warranties (16 C.F.R. Parts 701, 702 and 703): These rules apply only to warranties on **products costing more than $15**. Disclosures required include: specific wording, and additional specific wording, if implied warranties are disclaimed or damages are limited; both warrantors and retail sellers must make the full warranty text **available pre-sale**, through the use of one or more specified means. Those rules have the **force of law**; and violations may lead to FTC fines, mandated consumer protection and/or injunctions. Consumers may not enforce them.

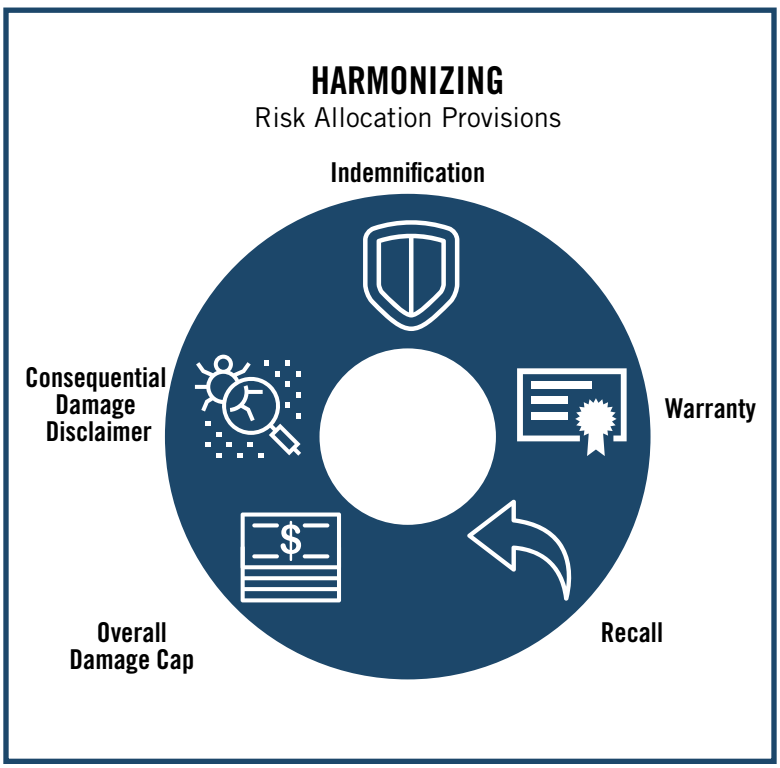


C. State Statutes.

There is a haphazard body of state legislation/regulations of consumer warranties on specific products (see, e.g., Wis. Stat. § 100.205, as to motor vehicle rustproofing warranties). Further, California has adopted a generally applicable statute (called the "Song-Beverly Consumer Warranty Act", Cal. Civ. Code § 1790 et seq.), notably adding that "warranty registration" cards, and even the use of that phrase, are prohibited. Most state "little FTC" laws permit consumers to make claims under the principles embodied in the FTC Magnuson-Moss rules.

D. General Federal Anti-Deception Law.

1. The Federal Trade Commission Act (15 U.S.C. § § 41-58) prohibits "unfair or deceptive acts or practices" generally; many states have similar laws.
2. On the subject of consumer warranty advertising, the FTC has adopted "guidelines" (16 C.F.R. Part 239) instructing:
   a. any mention of a written warranty should include reference to the availability of the full warranty text, pre-sale, at the place of sale, and
   b. if the word "lifetime" or "life" is used, an indication of what life is referred to should be included.
3. The guidelines are not enforceable by anyone as such; but failure to heed them can lead to FTC actions for injunctions against conduct that it considers unfair or deceptive. (State "little FTC" laws may be enforced by state attorneys general, and in some states directly by consumers.)



INDEMNIFICATION

Kate Wegrzyn

I. What is Indemnification?

According to Black's Law Dictionary (10th ed. 2014), indemnity is a "duty to make good any loss, damage, or liability incurred by another." At its core, an indemnification is a promise to reimburse a person for a loss incurred by that person. Often, the obligation to indemnify is limited to third party claims. Further, there is typically a "defend" component to the indemnity that requires the indemnifying party to take over the defense of the claim on behalf of the indemnified party. The following are a few of the common subjects of indemnities found in supply agreements:

- Negligence and willful misconduct.
- IP infringement.
- Failure to comply with law.
- Personal injury and tangible property damage.

II. Consistency with Limitation of Liability Provisions

One must always be mindful of the interplay of the risk allocation provisions in a contract. For example, if the agreement contains a broad indemnity stating the indemnifying party will indemnify the indemnified party against all losses resulting from specified causes, and also includes a consequential damage disclaimer providing that neither party will be responsible to the other party for consequential damages, the agreement has an inherent inconsistency, which is not good for either side because neither can depend on an outcome (that is, the indemnified party does not know if its reputational or other consequential losses will be indemnified, for example, and the indemnifying party does not know if it is responsible to indemnify for reputational or other consequential losses). As another example, third party claims are typically classifiable as a consequential damage. If an agreement contains both an indemnity for third party claims and a consequential damage disclaimer, an internal conflict exists in the agreement, potentially leaving it to a judge or jury to determine what outcome was intended by the parties. As a result, it is important to ensure that contracts expressly address how indemnification clauses and damage disclaimers interact with one another.

III. Indemnification vs. Warranty

How is an indemnification different from a warranty? A warranty and an indemnity are two different tools serving two different purposes.

A. First, an indemnity is usually broader than a warranty. A warranty typically only covers certain contractually prescribed (or implied by law) defects in a product, whereas an indemnity frequently covers a much more expansive array of concerns, like the negligence or willful misconduct of the indemnifying party that harms a third party who then brings a claim against the indemnified party (whether or not that negligence or willful misconduct relates to a product or a defect in a product).

B. Second, an indemnity typically includes an express requirement to defend the indemnified party against the claim incurred (such as, "Seller hereby agrees to indemnify, *defend*, and hold harmless Buyer

from and against…"), and expressly provides for the indemnifying party to cover attorneys' fees. Neither of these protections are usually afforded by a warranty.

C. Third, warranty remedies are typically limited to repair or replacement of the affected product at issue, or reimbursement of the purchase price paid by the buyer for the affected product. In contrast, indemnification obligations are often unlimited and expressly carved out from any overall damage caps in the contract.

INDEMNIFICATION VS. WARRANTY

Breadth	Typically broader than warranty	Often limited to the product
Defense Costs	Typically expressly covered	Not typically covered
Remedy	Often carved out of liability caps and disclaimers	Typically limited to repair, replace, or refund
Third Party Claims	Typically expressly covered	Not typically covered

IV. Indemnification Procedures

In addition to paying careful attention to the scope of the indemnification obligations themselves, it is also important to ensure that indemnification procedures are addressed:

A. **Notice of the Claim.** First, the indemnifying party will want to ensure that, when a claim is made against the indemnified party for which it will seek indemnification, the indemnified party provides prompt written notice to the indemnifying party of the claim.

B. **Control of the Defense.** Second, the indemnifying party should include a provision that gives it the right to have sole and exclusive control of the defense of the claim. The indemnifying party likely does not want to be in a position of having to reimburse the indemnified party for its defense costs and the cost of the settlement or judicial award; the indemnifying party typically would rather be in charge of the defense so that it can work to resolve the claim as quickly and cost-effectively as possible. The indemnified party may want to include a right to participate in the defense of the claim, at its own cost and subject to the right of the indemnifying party to control the defense.

C. **Requirement to Cooperate.** Often, the indemnified party will have access to key documents or witnesses that the indemnifying party needs for the defense of the claim. As such, it is important to include an express obligation on the indemnified party to cooperate fully with the indemnifying party's defense of the claim.

D. **Settlement Rights.** The indemnifying party wants the broadest possible settlement rights, while the indemnified party often pushes for the narrowest. A compromise is often reached with the indemnifying party having the right to settle without the indemnified party's consent if the settlement imposes only a monetary obligation to be paid by the indemnifying party (that is, no fault is ascribed to the indemnified party and no rights of the indemnified party are infringed).

CONSEQUENTIAL DAMAGE DISCLAIMERS AND LIQUIDATED DAMAGES

Kate Wegrzyn

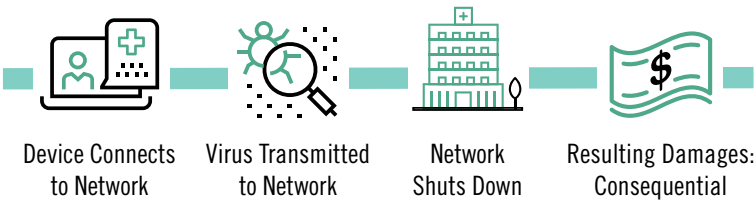
I. What are Consequential Damages?

Consequential damages are [l]osses that do not flow directly and immediately from an injurious act but that result indirectly from the act." Damages, Black's Law Dictionary (10th ed. 2014).

Let's take a straightforward example: If a purchased medical device that connects to a hospitals' system and transmits a virus, and the network shuts down and/or a data breach occurs, the resulting damages would be considered consequential damages. Note that, although the damages are consequential, in terms of the financial impact on you, they are no less real than the direct damages. The same is true in a commercial scenario; consequential damages are just as real and destructive as direct damages.

CONSEQUENTIAL DAMAGE DISCLAIMER

Easy Example



II. Examples of Consequential Damages

Below are common examples of consequential damages in a commercial context:

- Loss of anticipated profits;
- Loss of use of goods or services to be provided;
- Loss of business;
- Cost of unsuccessful attempts to repair defective goods;
- Loss of goodwill;
- Losses resulting from interruption of buyer's production process;
- Loss of reputation; and
- Loss of sales contracts because of delayed products.

III. Disclaimers of Consequential Damages

A. ***Permissibility of Limiting Consequential Damages.*** Consequential damages may be limited or excluded in a contract unless the limitation or exclusion is unconscionable. (Limitation of consequential damages for injury to the person in the case of consumer goods is prima facie unconscionable, but limitation of damages where the loss is commercial is not.) U.C.C. § 2-719(3).

B. When to Limit Consequential Damages. In theory, the definition of consequential damages is not that complicated, but in application, the results become muddled. Commercial contracts often include a consequential damage disclaimer, but one reason to resist such a disclaimer may simply be to avoid contentious and expensive litigation over whether a party's damages were direct or consequential in nature. Generally speaking, the buyer of a product or recipient of a service will want to resist a disclaimer (even a mutual disclaimer) of consequential damages, because such a disclaimer is much more likely to benefit the seller or service provider than the buyer or service recipient. For example, typically, the buyer's primary or only obligation under a supply agreement is to pay for the product, the failure to do which does not carry with it as much risk of consequential damages as the sale of a product creates for the seller. On the other hand, the seller of a product could be subject to a host of consequential damages in the event it fails to timely deliver the products or delivers defective products and, as such, the seller will want to push for a consequential damage disclaimer.

C. Personal Injury and Property Damages from Warranty Breaches. Article 2 of the U.C.C. provides that personal injury or property damage proximately resulting from any breach of warranty is a consequential damage. U.C.C. § 2-715(2)(b). As such, if a contract includes a consequential damage disclaimer, a buyer's warranty remedies will not help the buyer in the case where the product is defective and causes property damage (it should be noted that a warranty remedy provision may also provide for sole and exclusive remedies of repair/replace/refund; in such case the warranty remedies will not protect the buyer for such property damage claims, even in the absence of a consequential damage disclaimer).

D. Drafting Notes. The 1976 Seventh Circuit decision in *Berwind Corp. v. Litton Indus., Inc.,* 532 F.2d 1, has greatly influenced how practitioners draft liability limitations in contracts for the sale of goods, through its suggestions that practitioners should:

1. Separate liability limitations from warranties,
2. Make liability limitations **CONSPICUOUS,** and
3. Explicitly mention that liability limitations apply to "torts" and/or "negligence."

IV. Carve outs from the Consequential Damage Disclaimer

In most arm's-length commercial agreements between sophisticated parties, the parties will agree to include a consequential damage disclaimer that is subject to certain carve-outs that permit a party, in certain situations, to recover consequential damages from the other party. The most common carve-outs from a consequential damage disclaimer are as follows:

A. Third Party Indemnification Claims. Claims brought by third parties for which a party is entitled to be indemnified should be carved out from consequential damage disclaimers. If an indemnifying party commits an act for which it has provided an indemnity under the agreement (for example, an indemnity for claims arising from that party's negligent acts or omissions) and that act injures a third party who then sues the indemnified party, the indemnified party will expect to be held harmless from that suit. However, a claim by a third party (and the defense of such claim) is likely to be classified as a consequential damage with respect to the indemnified party. As such, an indemnity could be deemed overridden by a broad consequential damage disclaimer that does not properly exclude third party claims.

B. First Party Negligence and Misconduct. In addition to third-party indemnification claims (which may, depending on the indemnity provision, include third-party claims resulting from a party's negligence or willful misconduct), where bargaining power permits, the buyer should push for a separate carve-out from the consequential damage disclaimer for "first-party" negligence or willful misconduct. That is, if a party is negligent or acts with willful misconduct, and the other contractual party is injured as a result, the injured party should be entitled to recover all damages resulting from such negligence or willful misconduct, regardless of whether those damages are direct or consequential. As explained above, a consequential damage is still a real damage that a party must prove it has suffered. From the perspective of the buyer, there is no reason the seller should be excused from liability for such damages arising from that party's negligence or willful misconduct simply because the damages are consequential. It should be noted that, in states that have adopted the Economic Loss Doctrine, this carve-out will not be sufficient to preserve a claim for economic losses resulting from the failure of a product, even if it was negligently designed or manufactured. To recover those types of losses in such states, the parties will need to include an indemnity for first-party negligence and willful misconduct or carve such losses out from the sole and exclusive remedy provisions of the warranty. Sellers' perspectives are, of course, often entirely different. They do not expect to bet their companies on whether they can successfully defend a claim that they negligently designed or manufactured a product sold to a single customer, so sellers typically will want a consequential damage disclaimer to cover first-party negligence claims.

C. First Party Intellectual Property Infringement. Where intellectual property is involved, the indemnity should include an indemnification by the seller for infringement of the intellectual property rights of a third party. If so included as an indemnity, these third party claims will already be carved out from the consequential damage disclaimer by virtue of the first carve-out listed above. However, where buyer's intellectual property is involved, the buyer should also push for

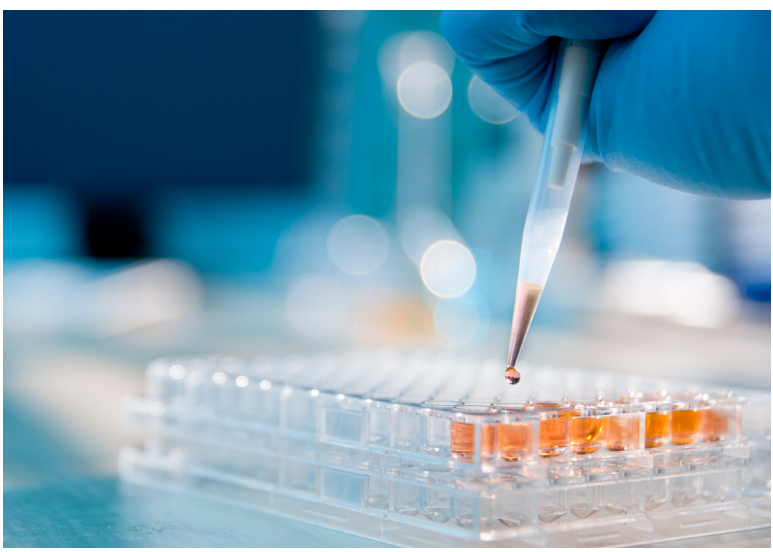
a carve-out for damages incurred by the buyer as a result of an infringement by the seller of the buyer's intellectual property rights. The damages resulting from an infringement of intellectual property rights are often going to be consequential (for example, lost profits or loss of market share). As such, for a buyer to have an adequate remedy for infringement by the seller of the buyer's intellectual property rights, first party intellectual property infringement would need to be excluded from the consequential damage disclaimer.

D. Product Recall. If a buyer needs to conduct a product recall or other field corrective action, the buyer may incur expenses that far exceed the cost of replacing, repairing or refunding the price of the product (which would be the direct damage, and which often are the sole remedies for a warranty claim). For example, there may be fines by regulatory agencies, money spent canvassing to reach purchasers, internal costs of employees dedicating time to the recall, attorneys fees, and costs of field work, among others. Buyers should attempt to exclude such recall-related expenses and losses from the scope of any consequential damage disclaimer.

E. Breach of Confidentiality. The reason for carving damages arising from a breach of confidentiality out of a consequential damage disclaimer is that the bulk of damages that arise from a breach of confidentiality will, in fact, be consequential. As with intellectual property infringement claims, in order for a party to have an adequate remedy for a breach of the confidentiality provisions, damages resulting from breaches of confidentiality must be excepted from the consequential damage disclaimer.

V. Liquidated Damages

The U.C.C. permits liquidated damages, but only at an amount which is reasonable in the light of the anticipated or actual harm caused by the breach, the difficulties of proof of loss, and the inconvenience or nonfeasibility of otherwise obtaining an adequate remedy. A term fixing unreasonably large liquidated damages is void as a penalty. U.C.C. §2-718(1). In appropriate circumstances, parties may want to negotiate reasonable liquidated damage clauses to address delays in delivery, performance shortfalls, or other breaches. Such clauses can give both parties a degree of certainty with respect to the consequences of the breaches in question.



WHEN ANTITRUST LAW AND ROUTINE COMMERCIAL TRANSACTIONS INTERSECT

Rich Casper

I. What are the Relevant "Antitrust Laws"?

A. Sherman Act § 1. In the U.S., Section 1 of the Sherman Act (15 U.S.C. § 1) is the most fundamental of them. Its deceptively simple language prohibits "[e]very contract, combination… or conspiracy, in restraint of trade or commerce," but the determination of the meaning of that language occupies the bulk of antitrust case law.

B. Clayton Act § 3. Section 3 of the Clayton Act (15 U.S.C. § 14) prohibits, in certain circumstances, exclusive dealing agreements (which may also be challenged under Section 1) and the "tying" of sales of one product to the buyer's agreement to purchase another of the seller's products.

C. Robinson-Patman Act. Section 2 of the Clayton Act (15 U.S.C. § 13), which is usually referred to as the Robinson-Patman Act (the name given to the amendatory legislation that created it), prohibits certain types of discrimination in connection with the sale of "commodities."

D. Federal Trade Commission Act § 5. Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45) prohibits "[un]fair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce."

E. State Legislation. Various state laws address the same subjects. In many cases, the difference between the practical effects of those laws and their federal counterparts are little more than that the state laws apply to purely intra-state practices. In other cases, for example some of the "little FTC Acts", the states create private causes of action that are not present under Section 5. In still others, e.g., MD Code Ann., Com. Law § 11-204(a) (which absolutely prohibits minimum resale price fixing), states have prohibited practices that might be legal under federal law.

II. What Specific Practices does Section 1 Regulate?

A. Multiple Actors Required. Section 1 only covers multi-party arrangements. It does not apply to unilateral conduct, for example a supplier's choice not to sell to another person interested in buying. It also does not apply to arrangements between companies affiliated by ownership of equity.

B. The Rule of Reason. In the earliest U.S. Supreme Court decisions applying Section 1, the Court noted that the literal breadth of Section 1 would prohibit all commercial contracts, as every sale restricts other sales by limiting what can be sold to others. To avoid this absurd result, the Court interpreted Section 1 as prohibiting only "unreasonable" restrictions, with reasonableness determined by a weighing of the benefits of the restriction against the extent of its detriment. This analysis came to be known as the "rule of reason."

C. The Per Se Rule. Because rule of reason analysis is fact-intensive and inherently subjective, the Court later adopted a shortcut category for commercial practices that it judged so inherently detrimental

to commerce that they could not be justified by any countervailing benefit. Such restrictions were pronounced "per se" illegal.

D. Horizontal Restraints. The paradigm of a per se restraint is an agreement between competitors or potential competitors (often called a "horizontal" agreement), as to prices that they charge, a category that includes customer and territorial allocations between competitors. Such agreements are frequently attacked as criminal violations of the antitrust laws.

E. Vertical Restraints. In contrast, restraints in agreements between suppliers and their customers ("vertical" agreements) are analyzed under the rule of reason and seldom lead to criminal prosecution.

F. Extraordinary Remedies. Aside from criminal penalties, violations of Section 1 can result in injunctions and civil suits by regulators and by private parties injured by prohibited conduct; in private actions, a successful plaintiff will be entitled to recover treble damages (three times the damages proven), and its attorneys' fees.

G. Vertical Price Fixing. For many years, vertical price fixing agreements were considered per se illegal. That changed as a result of a series of Supreme Court decisions. However, while federal law analyzes all vertical price fixing under the rule of reason, some states may not follow the same principle in applying state antitrust laws, most notably under the Maryland statute prohibiting minimum resale price fixing agreements altogether (see citation in subdivision 1.E above).

H. "MAP" Policies. Minimum advertised price (generally called "MAP") policies were developed to skirt the former per se illegality of minimum resale price fixing. They did that by (1) prohibiting only advertising of prices below an established minimum, not sales at such prices, and (2) avoiding any interactive involvement of a supplier's customers, i.e., the supplier notifies the customers of the policy, does not ask for the customers' agreement to it and refuses to discuss it with customers.

I. Inferential Proof. Almost all horizontal antitrust violations are proven by inference from the parties' conduct (i.e., not from express agreements). Thus, an exchange of price information between competitors, followed by similar pricing by the companies involved, is an example of proof of a horizontal price fixing agreement.

COMMERCIAL TRANSACTIONS AND THE ANTITRUST LAWS

What Law Applies

	Sherman Act	Robinson-Patman Act	State Statutes	Clayton Act	FTC Act
Consumer Warranties			■		■
Labeling			■		■
Advertising		■	■		■
Pricing	■	■	■		
Distribution and Supply Chain Agreements	■	■	■	■	

III. What does the Robinson-Patman Act Cover?

A. Section 2(a). Section 2(a) prohibits discrimination in the prices that a seller charges to its customers, in certain circumstances. It is to be stressed that, although the favored purchasers are the ones who benefit from the discrimination, the primary target of the statutory prohibition is the discriminatory seller.

B. Difficulties in Section 2(a) Cases. Section 2(a) cases are complicated by the number of elements of the offense, including particularly the need to prove "injury to competition", and by the number of defenses. They are therefore difficult for a plaintiff to win, and expensive for both sides.

C. Elements of the Offense. The elements of a claim are actual sales (e.g., not one sale and one offer to sell) to two different purchasers, at least one of which crosses state lines, the sales must be of goods (not services or other intangibles), the goods in the two sales must be of "like grade and quality", the sales must have been "reasonably" contemporaneous, the prices must have been different, and the price difference must have caused injury to competition, not merely injury to the disfavored purchaser (so, unless the seller's product is a significant component of the costs of the purchasers' businesses, e.g., where the purchasers are competing resellers, there will not likely be a violation).

D. Defenses. Even if all of those elements are satisfied, the price difference will not violate Section 2(a) if any of the following defenses is proved by the seller:

- The lower of the prices was provided to meet (not beat) a competitive price available to the favored purchaser,
- The cost to the seller of making the sale to the favored purchaser was lower than the cost of selling to the disfavored purchaser, by the amount of the price difference,
- The price difference is attributable to changes in market conditions,
- The favored purchaser performs services relating to the resale of the goods, e.g., warehousing or warranty coverage, that the disfavored purchaser does not perform, and the value (or cost to the favored seller) is approximately the same as the price difference, or
- The lower price was offered to the disfavored purchaser and could, as a practical matter, have been accepted by the disfavored purchaser; obviously this will usually be in the context of offering a lower price on some condition such as buying in a particular minimum volume (but note that smaller customers may not be disfavored for refusing to buy in volumes they cannot use).

E. Non-Profit Examption. Sales to non-profit businesses are generally exempt from Section 2(a) of the Robinson-Patman Act.

F. Section 2(c). Section 2(c) was an amendment to the Robinson-Patman Act designed to prevent sellers from circumventing Section 2(a) by paying purchasers' agents, including employees. The wording of the statute, however, also prohibits commercial bribery by sellers. Further, neither the elements nor the defenses applicable to Section 2(a) apply to the conduct prohibited by Section 2(c). Thus, it is almost always better for a seller to charge a lower price to a complaining customer than to agree to make payments to an agent of the customer.

G. Discrimination in Promotional Assistance. Sections 2(d) and (e) require that a seller offering assistance to competing resellers in connection with their resale of the seller's products do so on

a "proportionately equal" basis. (This requirement applies to protect both resellers that buy directly and those that buy from intermediaries, such as distributors.) The typical arrangement addressed by this requirement is a co-op advertising program under which the seller contributes to the cost of its customers' advertising. The benefits of such a program must be equally useful, as a practical matter, to smaller resellers, although the value of using the program is expected to be in proportion to the resellers' purchase volumes. Again for Section 2(d) and (e) claims, for the most part neither the defenses to a Section 2(a) claim, nor its associated elements, apply.

H. "Fred Meyer" Guides. The FTC has published guidelines about how to draft and administer compliant promotional assistance programs.

I. Exemption for Sales to Federal Government. Sales to the federal government are exempt from the Robinson-Patman Act, but not sales for resale to the federal government.

J. J. Extraordinary Remedies. As is the case in Sherman Act Section 1 cases, a successful Robinson-Patman plaintiff can recover treble damages and attorneys' fees.

IV. What does the Federal Trade Commission Act Cover?

A. Unfair or Deceptive Acts. As noted above, this Act prohibits the general category of "unfair or deceptive" acts or practices. It is enforced exclusively by the U.S. Federal Trade Commission (the "FTC"), though as also explained above, private causes of action for violation of state "little FTC" statutes exist in many states. In carrying out its statutory mandate in areas also regulated by the FDA, the FTC generally defers to FDA expertise within the FDA's sphere of activity, including drug and medical device labeling, but (in cooperation with the FDA) exercises primary responsibility for preventing deception in advertising such products.

B. FTC Rules. Under the authority granted to the FTC, it has adopted a number of formal rules, the violation of which carry specific monetary penalties without resort to the courts. Among the broadest of those rules are those regulating written consumer warranties, "mail-order" (including internet) sales, and the sale of franchises (requiring extensive disclosures).

C. FTC Informal Guidance. The FTC has also provided less formal guidance on numerous topics relating to the advertising and labeling of products, including:

- The "Green Guides", concerning environmental marketing claims,
- Guides regarding the use of endorsements and testimonials in advertising,
- A policy concerning representations that products are of U.S. Origin, and
- A policy regarding substantiation of advertising claims generally.

The FTC and the U.S. Department of Justice have issued a joint policy statement addressing both the principles that they will adhere to and the methods that they will use in enforcing the antitrust laws in the healthcare industry. That statement focuses primarily on mergers and other collaborative activities in the industry.

D. Ancillary Use of FTC Guidance. The guidance provided by the FTC is very influential as a source of law in challenges to advertising in various contexts, including voluntary adjudication by the National Advertising Division of the Better Business Bureau, enforcement actions by other agencies having ancillary jurisdiction (e.g., the FDA and the USDA), and class actions under state statutes and common law theories.

NON-DISCLOSURE AGREEMENTS

Kate Wegrzyn and Heba Hazzaa

I. Is a Non-Disclosure Agreement ("NDA") Necessary?

When considering entering into an NDA, the first question to ask is whether it is necessary for either party to be disclosing confidential information. If you must disclose your confidential information to another party, an NDA is a helpful tool to protect that information, but the best way to protect your confidential information is to not disclose it at all. Conversely, consider whether and how much confidential information you need to receive from the counterparty. Once you receive a party's confidential information, if you are bound by an NDA, you have committed to protecting that information under the terms of that NDA.

II. Scope of the Definition of "Confidential Information"

When considering the scope of the definition of "Confidential Information", you should consider the following question: "Who is disclosing Confidential Information?"

A. Neither Party is Disclosing Confidential Information. There is no need to execute an NDA.

B. Only You are Disclosing Confidential Information.

1. Sign a one-way confidentiality agreement, where only the other party is agreeing to not use or disclose your confidential information.
2. Define "Confidential Information" broadly, perhaps even including language that "Confidential Information" includes information "reasonably believed" by you to be confidential.

C. Only the Other Party is Disclosing Confidential Information.

1. Define "Confidential Information" as narrowly as possible so that you can more easily avoid violating the NDA. For example, you could have the definition only pertain to information relating to some defined subject matter (like the "potential development of X product") and further require that, for any information to be deemed to be Confidential Information, the information must be conspicuously labeled **"CONFIDENTIAL"** at the time it is disclosed to you.
2. Ensure there is a carve-out to the non-use/non-disclosure obligations for legally required disclosures. As a drafting note, this should be an exception to the non-use/ non-disclosure obligations, not an exclusion from the definition of "Confidential Information." The distinction here is that such information should still generally be treated as confidential even though its disclosure is legally required in a specific situation.

D. *Both Parties are Disclosing Confidential Information.*

1. Use a two-way NDA.
2. Draft the definition of "Confidential Information" with a balance of the above concepts in mind – you want to draft it narrowly enough that you do not unwittingly violate your obligations to not use or disclose the other party's Confidential Information, but not so narrowly that your Confidential Information is not properly protected. You also want to weigh the risk of losing the ability to sell in the marketplace if the definition is too broadly crafted.

III. Exceptions to the Definition of "Confidential Information"

Ensure the necessary exceptions to what constitutes "Confidential Information" are included. The most common such exceptions are as follows:

- Information that is already in the public domain at the time it is disclosed, or that subsequently enters the public domain without breach of the NDA;
- Information that you already know at the time it is disclosed pursuant to the NDA;
- Information that a third party rightfully tells you; and
- Information that you independently develop without reference to the other party's Confidential Information.

IV. Disclosure vs. Use

A. A party receiving Confidential Information is typically permitted to use that Confidential Information only for the purposes identified in the NDA.

B. The prohibition of disclosure should be absolute (that is, the receiving party should not be permitted to disclose Confidential Information for any reason), other than when legally compelled.

V. Confidentiality Period

A. A requirement not to disclose or use the Confidential Information of another party is a restrictive covenant and, like other restrictive covenants, must aim to protect a legitimate business interest. An NDA's restrictions should be no more restrictive than reasonably necessary. To increase the likelihood that the NDA will be enforceable, consider including a time period during which a party has to maintain the confidentiality obligations under the NDA. Depending upon the circumstances, including a confidentiality period that extends for one year after the term of the applicable agreement is generally considered to be a safe length of time. However, the duration of restrictions should be carefully researched and considered on a case-by-case basis.

B. Additionally, the confidentiality period should treat trade secrets separately from other types of Confidential Information, such that, despite any general expiration of the non-use/non-disclosure obligations under the NDA, the receiving party's obligations with respect to trade secrets will remain in effect for as long as they remain trade secrets under applicable law.

VI. Requirement to Return Confidential Information

An NDA should include a provision requiring that Confidential Information be returned (or destroyed) upon demand by the disclosing party and, in any event, upon termination of the NDA.

VII. Other Terms

On occasion, a party may try to use an NDA as a means to bind the other party to terms that are not typically found in an NDA. For example, a party may include non-competition, non-solicitation and/or non-circumvention provisions in an NDA. Or a seller entering into an NDA with a buyer may include a cross reference incorporating its standard terms of sale in order to bind the buyer to those terms for future product sales. Be on the lookout for these provisions.

VIII. Dispute Resolution Clauses in NDAs

Given the nature of NDAs, you might want to consider arbitration to avoid having to litigate the confidential aspects of your agreement in court. Arbitration is a process by which the parties select the arbitrator(s) who will resolve the dispute by a binding and enforceable decision outside of court in accordance with the parties' agreement. In your dispute resolution clause, you can agree beforehand on the number of arbitrators, their area of expertise (if necessary), the location of the hearings, and the applicable law, among other things.

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ABOUT THE TEAM

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