# Medical Device Manufacturer
# Compliance Risk Area Summary

JD HealthCare Partners, LLC
Compliance Consulting • Risk Management

| | Compliance Risk Area | Effective Date | Applies To: | Risk/Penalties | Requirements |
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| 1 | **Physician Relationships: Federal Anti-Kickback Statute**<br>**Explanation:** The Anti-Kickback Statute imposes civil and criminal penalties when anything of value is provided to a referring party in exchange for a referral of a federal health care program beneficiary. Typically the referring party is a physician, but the statute includes ANY referring party. If any reason for a device manufacturer to provide something of value to a surgeon is to induce a referral, then the statute is violated. There are safe harbors that exclude from prosecution some narrow relationships between parties. | 1972 | Any individual or entity, including the Company, physicians and Company employees | 1. Civil - $25,000<br>2. Criminal – 5 years in prison<br>* - False Claims Act penalties also apply | 1. Payment or offer to provide something of value;<br>2. In exchange for a referral of Federal health care business;<br>3. Where at least one purpose is to induce future referrals. |
| 2 | **Physician Relationships: Stark Law**<br>**Explanation:** The Stark Law makes it illegal for a physician to refer a Medicare patient for designated health services (DHS) to a company with which the physician or a family member has a financial relationship. DHS includes a list of 12 services including durable medical equipment and supplies (7) and prosthetics, orthotics, and prosthetic devices and supplies (9). It is unclear whether an implanted medical device falls under the definition of DHS. However, because Stark violations also violate the Anti-Kickback Statute, compliance with Stark helps to avoid violating the Anti-Kickback Statute. | 1989 | Physicians and the Company | Civil - $15,000<br>* - False Claims Act penalties also apply | 1. Physician;<br>2. Any financial relationship;<br>3. Designated health services (including prosthetic, orthotics, prosthetic devices, and supplies). |
| 3 | **Physician Relationships: Sunshine Act Reporting**<br>**Explanation:** As part of the Affordable Care Act, payments, including investment interests, that are made to physicians and their family members must be reported annually to CMS by device manufacturers including the nature of the payment, the recipient, the date of the payment, and the amount. | 2013 | The Company, physicians (including family members), and teaching hospitals | Civil Monetary Penalties (Up to $10,000) | 1. Device or pharmaceutical manufacturer;<br>2. Payment, meal, gift, or investment interest;<br>3. To a physician or teaching hospital. |
| 4 | **Physician Relationships: Physician Contracts**<br>**Explanation:** One Anti-Kickback Statute safe harbor and an exception to the Stark Law is for personal service contracts between physicians and services providers (designated health service providers under Stark). The primary requirements for a personal services agreement include: (1) must specifically spell out the services to be provided, (2) must have a term of at least one year, and (3) the amount of compensation is: (i) established in advance, (ii) consistent with fair market value, and (iii) not tied in any manner to the volume or value of referrals or business generated by the | 1989 and 1992 | Any individual or entity, including the Company, physicians and Company employees | Same as Anti-Kickback and Stark penalties above | 1. Written agreement;<br>2. Specifically spells out the services to be provided;<br>3. Term of at least one year; and<br>4. The amount of compensation is:<br>i. established in advance,<br>ii. consistent with fair market value, and<br>iii. not tied in any manner to the |

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| | provider. Contracts that do not meet these criteria are not illegal per se, but pose an elevated risk to the device manufacturer. To reduce risk associated with physician contracts, all payments made to a physician by a device manufacturer should be made pursuant to a fully executed contract that meets the requirements listed above. | | | | volume or value of referrals or business generated by the provider. |
| 5 | **False Claims Act: Off-Label Promotion**<br>**Explanation:** Physicians are permitted to use or prescribe pharmaceuticals and/or devices in a manner that will best meet the needs of the patient even if the use or prescription has not been approved by the FDA. Device manufacturers may only communicate the uses of its products that are consistent with FDA approvals. As such, materials or communications from a device manufacturer that promote or in any way encourage physicians to use or prescribe a product in a manner that has not been approved by the FDA may subject the device manufacturer to a claim of off-label promotion. The government views off-label promotion as a Federal False Claims Act violation because the use of the device was based on information that was not approved by the FDA and therefore illegitimate as a basis for billing Federal health care programs. False Claims Act violations can result in civil and criminal penalties. If the FDA finds that off-label promotion has occurred, it can issue "Warning Letters" to the device manufacturer. Failure to comply with a Warning Letter can result in a referral by the FDA to the Department of Justice. In addition, the FDA has the authority to impose civil monetary penalties for device manufacturers for false or misleading advertisements. | 1938, updated 1997 | The Company | Warning letter and potential criminal penalties, plus False Claims Act civil and criminal penalties | 1. Marketing or promotion;<br>2. Medical device or pharmaceutical;<br>3. For a use not approved by the FDA. |
| 6 | **False Claims Act: Billing and Reimbursement Advice**<br>**Explanation:** The Federal False Claims Act imposes civil and criminal penalties on any person (including corporations) who submit a claim to the Federal government for payment knowing that the claim, or the basis for the claim, was false, fictitious, or fraudulent with the intent to defraud the government (repeated submissions have been deemed to satisfy the intent requirement). If a party submits a claim for payment that is based on inaccurate reimbursement advice, then the basis for the claim is false, fictitious, or fraudulent and the claim is considered a false claim. Repeated submissions of claims based on the same inaccurate reimbursement advice would be considered to meet the intent requirement. The Deficit Reduction Act of 2005 tied Medicaid funding to State enactment of false claims act laws. As a result, almost every state | 1863 | The Company | $11,000 per claim plus 3 x the amount of damages | 1. Claim for payment to a Federal health care program;<br>2. False or fraudulent;<br>3. Knowledge (express or implied) that the claim was false. |

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| | has its own false claims act similar to the Federal False Claims Act. | | | | |
| 7 | **False Claims Act: Improper Physician Relationships**<br>**Explanation:** The Federal False Claims Act has been applied to payments made to device manufacturers from physician use where the physician use was determined to be a result of an inappropriate relationship (similar to the Anti-Kickback Statute). The basis for this application is without the inappropriate relationship between the device manufacturer and the physician, the physician would not have used the device and therefore it was not medically necessary. Because the device was not medically necessary, the claim for payment was based on false, fictitious, or fraudulent information. Civil and criminal penalties may be applied in such cases. The only evidence necessary is a relationship between the device manufacturer and the physician that falls outside of a safe harbor or exception and a claim for payment submitted or caused to be submitted by the physician for which the device manufacturer receives payment. | 1863 | The Company | $11,000 per claim plus 3 x the amount of damages | 1. Claim for payment to a Federal health care program;<br>2. False or fraudulent;<br>3. Knowledge (express or implied) that the claim was false. |
| 8 | **Physician Owned Distributorships**<br>**Explanation:** Physician-Owned Distributorships (PODs) are considered a risk for Anti-Kickback Statute and Federal False Claims Act violations because there is an inherent incentive by the physician owners to promote the use and sale of the products they distribute. Device manufacturers are typically not associated with the PODs unless the device manufacturer is also a distributor. However because of the increased scrutiny on PODs, some hospitals and surgery centers are reluctant to do business with device manufacturers that have physician owners because they are incorrectly classifying device manufacturers as PODs. In addition, device manufacturers that have relationships with distributors that have physician ownership may also be at risk if there is any agreement or arrangement between the device manufacturer and the physician, e.g., consulting agreement. | 2013 | Company-contracted distributors with physician ownership and, in some cases, the Company if there are physician investors | See Anti-Kickback Statute and False Claims Act penalties | 1. Distributorship;<br>2. Physician ownership; and<br>3. Physician-owner use/prescribing of products sold by distributor |
| 9 | **Foreign Corrupt Practices Act (FCPA)**<br>**Explanation:** The FCPA makes it illegal for persons and entities, directly or through agents, to make payments to foreign government officials to assist in obtaining or retaining business. Publicly traded companies must also keep records and have an adequate system of internal accounting controls to track the transactions of the corporation. Civil and criminal penalties may be imposed for violations. To violate the FCPA, the | 1977 | The Company, Company employees, and foreign distributors | Criminal<br>$250,000 (corporation)<br>$25,000 and 5 years in prison (individual)<br><br>Civil<br>$16,000 per violation | 1. American company;<br>2. Foreign government employee or official;<br>3. A payment; and<br>4. An intent to wrongfully influence or obtain business. |

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| | government official is not necessarily a high-level official and not necessarily one who makes the determination of whether business is directed to the person or entity. | | | (corporation and individual) | |
| 10 | **Distributor Relationships**<br>**Explanation:** The risk areas listed above apply to device manufacturers. However, where distributors are used to sell or promote the sale of a manufacturer's products, the device manufacturer is responsible for the conduct and activities of the distributor. For that reason a violation of any law by the distributor while selling the manufacturer's products can be attributed to the manufacturer and the manufacturer can face the civil and criminal penalties. | Included Above | Included Above | Included Above | Included Above |
| 11 | **PhRMA Code/AdvaMed Code Compliance (CA and NV only)**<br>**Explanation:** The California Legislature passed a law requiring pharmaceutical manufacturers to comply with the PhRMA Code and to attest annually that they are in compliance with the PhRMA Code. The definition of "drugs" contained in the law was written to include medical devices. As a result, in California, device manufacturers must attest annually to their compliance with the PhRMA code even though the PhRMA Code applies to interactions between pharmaceutical companies and health care professionals. The Nevada Legislature passed a law that requires both pharmaceutical and device manufacturers to develop a marketing Code of Conduct or adopt either the PhRMA Code or the AdvaMed Code. In addition, device manufacturers must annually submit their Code of Conduct or attest that they have adopted either the PhRMA or AdvaMed Code in its entirety. | 2009 | Pharmaceutical and device manufacturers in California and Nevada, physicians and family members | Civil penalties (CA) or Board of Pharmacy action (NV) | <u>California</u><br>1. Device manufacturer;<br>2. Compliance with PhRMA Code;<br>3. Annual declaration of compliance; and<br>4. Post the declaration on the company's website.<br><br><u>Nevada</u><br>1. Device manufacturer;<br>2. Marketing Code of Conduct or AdvaMed/PhRMA Code Adoption;<br>3. Annual attestation;<br>4. Submitted to the Nevada Board of Pharmacy. |