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Collaborating with Health Care Professionals

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Significant Federal Laws

- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))
  - Prohibits the offering, paying, soliciting or receiving any remuneration in return for
    - business for which payment may be made under a federal health care program; or
    - inducing purchases, leases, orders or arranging for any good or service or item paid for by a federal health care program
  - Remuneration includes kickbacks, bribes and rebates, cash or in kind, direct or indirect.
- Stark – Physician Self Referral Law
  - ***Does Not Apply to Manufacturers***

Physician Owned Distributors (PODs)

- PODs are ***not*** per se prohibited
- June 2011 Senate Finance Committee Minority Staff issued a report (Hatch Report) criticizing PODs
- September 13, 2011 letter from OIG to Committees outlined scope of a national study on spine implant PODs
- Efforts by Congress to limit the ability of ACOs and others to purchase from PODs

PPACA – Health Reform

- Section 6002 of PPACA included provisions from the Physician Payment Sunshine Act ("Sunshine Act") and requires "applicable manufacturers" to report annually certain "payments or other transfers of value" provided to a "covered recipient"
  - "Applicable manufacturer" defined as "a manufacturer of a covered drug, device, biological, or medical supply" operating in the US
  - "Payments or other transfers of value" is defined broadly
  - "Covered recipient " includes physicians and teaching hospitals
- First report due by March 31, 2013 and annually thereafter with first report to include data for January 1, 2012 – December 31, 2012
- Secretary was to have promulgated regulations by October 1, 2011 *(still waiting)*
- Secretary must make the reported information publicly available in a searchable format on its website by September 30, 2013 and on June 30th each year thereafter

Information to be Reported

- For each payment or other transfer of value, the following information must be reported
  - Covered recipient's name, business address, specialty and Medicare billing number (if applicable)
  - Amount of payment or transfer
  - Date of payment or transfer
  - Description of the form of payment (.g., cash, cash equivalent)
  - Description of the nature of payment (e.g., consulting fees, gifts)
  - Name of the covered drug, device, biological, or medical supply if "related to marketing, education, or research"
  - Any other categories of information required by the Secretary

Exceptions from Reporting

- Exclusions include the following:
  - Anything with a value of less than $10 but only if the aggregate amount provided to a covered recipient by a manufacturer does not exceed $100 per calendar year
  - Free product samples intended for patient use
  - Educational materials that directly benefit patients or intended for patient use
  - Covered recipient is a patient and not acting in his/her professional capacity
  - Discounts and rebates
  - In-kind items provided for charity care
- *Note:* no exclusion or delayed reporting for payments or other transfers of value in connection with any clinical trials or other research
  - However, delayed publication of such information by Secretary

AdvaMed and PhRMA Codes

- Both have adopted Codes on "Interactions with Healthcare Professionals" that address many of the same categories of issues (e.g., consulting arrangements, third-party educational conferences)
- Examples of how the Codes are "same … but different":
  - Location of Informational Sessions
    - PhRMA – Limited to in-office/in-hospital settings
    - AdvaMed – Settings conducive to effective transmission of information
  - Scholarships for those "In Training"
    - PhRMA – Includes a caveat not included in AdvaMed that selection of individuals is to be made by academic or training institution (and not manufacturer)
- Application of Codes to combination products?

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Voluntary Self-Disclosure:

Who, When, When Why and How?

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Why Voluntarily Disclose?

- Penalties for non-disclosure
- Controlling the process one's destiny
  - No subpoena/no raid
  - The reality of the whistleblower
  - Internal Investigation (documents and quantification)
- More favorable treatment
- Is it now the industry standard?
- The "sleep at night" factor

If Disclose, To Whom and When?

- To Whom?
  - Local U.S. Attorney's Office
  - Department of Justice in DC
  - OIG
- When?
  - Upon discovery of issue?
  - Upon preliminary review and confirmation of issue?
  - Upon full investigation and quantification?
- Considerations
  - First swipe at magnitude often over-broad, suggesting greater liability than warranted
  - Earlier disclosure can avoid duplication of effort but later disclosure can lead to quicker resolution
  - Whistleblower lawsuits and other threats to "voluntary" nature of disclosure
  - Government timetables

What and How to Disclose?

- An inaccurate, incomplete or otherwise misleading disclosure can be worse than no disclosure at all
- Presentation is important
- How much detail to present?
  - Less is more … Or is it?
  - Consider whether materials presented raise new issues
  - Explaining missing information or materials
  - Personal meetings vs. written submission