



# Mini Summit III: *Sunshine Compliance for Medical Device Companies*

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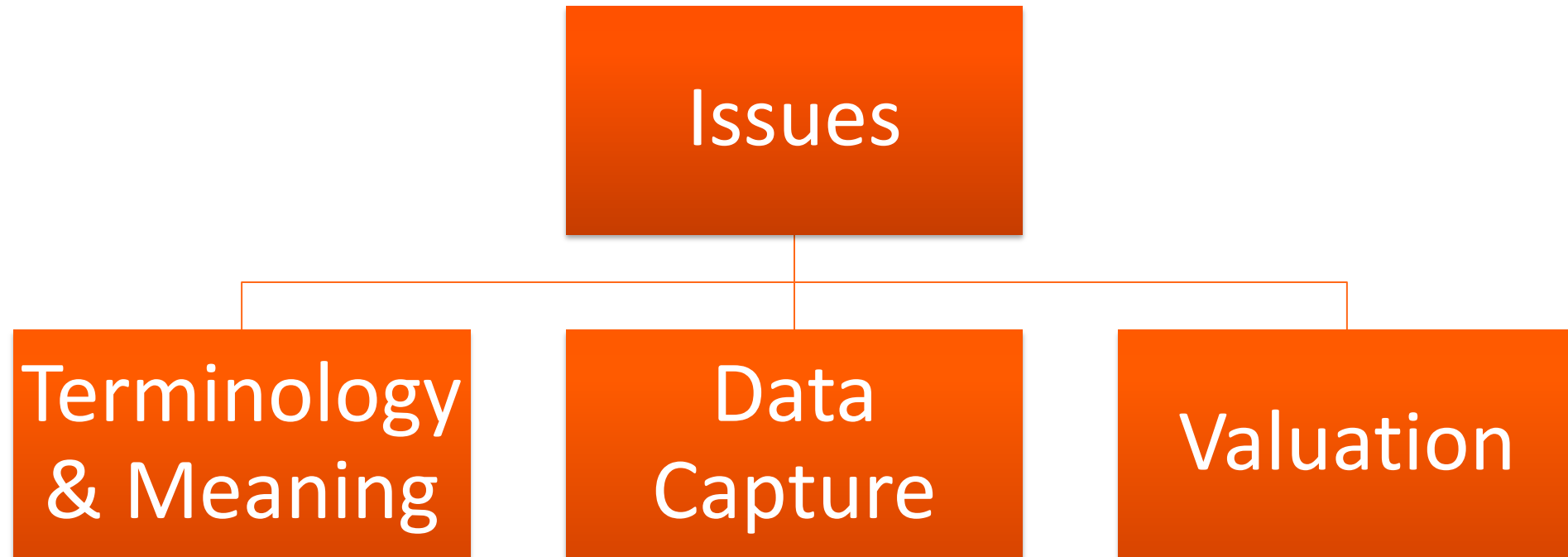
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- Evaluation, Demonstration and Loaner Units
- Group Spend
- Instrumentation & Multi-Product Distributors
- Significance of Data on Medical Device Enforcement



# EVALUATION, DEMONSTRATION AND LOANER UNITS



## AdvaMed Code

- No specific reference to loan of devices
- Evaluation Products
  - Typically used in patient care
  - Allows HCPs to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future
  - Includes **single use** (e.g., consumable or disposable products) and **multiple use** products (sometimes referred to as ‘capital equipment’)
- Demonstration Products
  - Typically NOT used in patient care
  - Used for HCP and patient awareness, education, and training

## MDMA Code

- “No-charge loaners” may be provided “to permit evaluation of products by Customers unfamiliar with the product,” “but only for a reasonable evaluation period”
- No specific reference to demo or evals

# Loaner Units: Terminology & Meaning – Statute/Reg

	Federal	Massachusetts	Vermont
<b>Demo &amp; Eval Units</b>	<ul style="list-style-type: none"> <li>Not referenced</li> </ul>	<p><b>Don't report:</b> "...medical device <b>demonstration</b> and <b>evaluation</b> units provided to a health care practitioner to assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future."</p>	<p><b>Report</b> as not-banned gift: "...medical device <b>demonstration or evaluation units</b> to a health care provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future."</p>
<b>Loaner Units</b>	<p><b>Don't report</b> "The <b>loan of a covered device</b> for a short-term trial period, not to exceed <b>90 days</b>, to permit evaluation of the covered device by the covered recipient."</p>	<p>No specific reference to loans of devices.</p> <p>Same as demo/eval?</p>	<p><b>Report</b> as not-banned gift "The <b>loan of a medical device</b> for a short-term trial period, not to exceed <b>120 days</b>, to permit evaluation of a medical device by a health care provider or patient."</p>

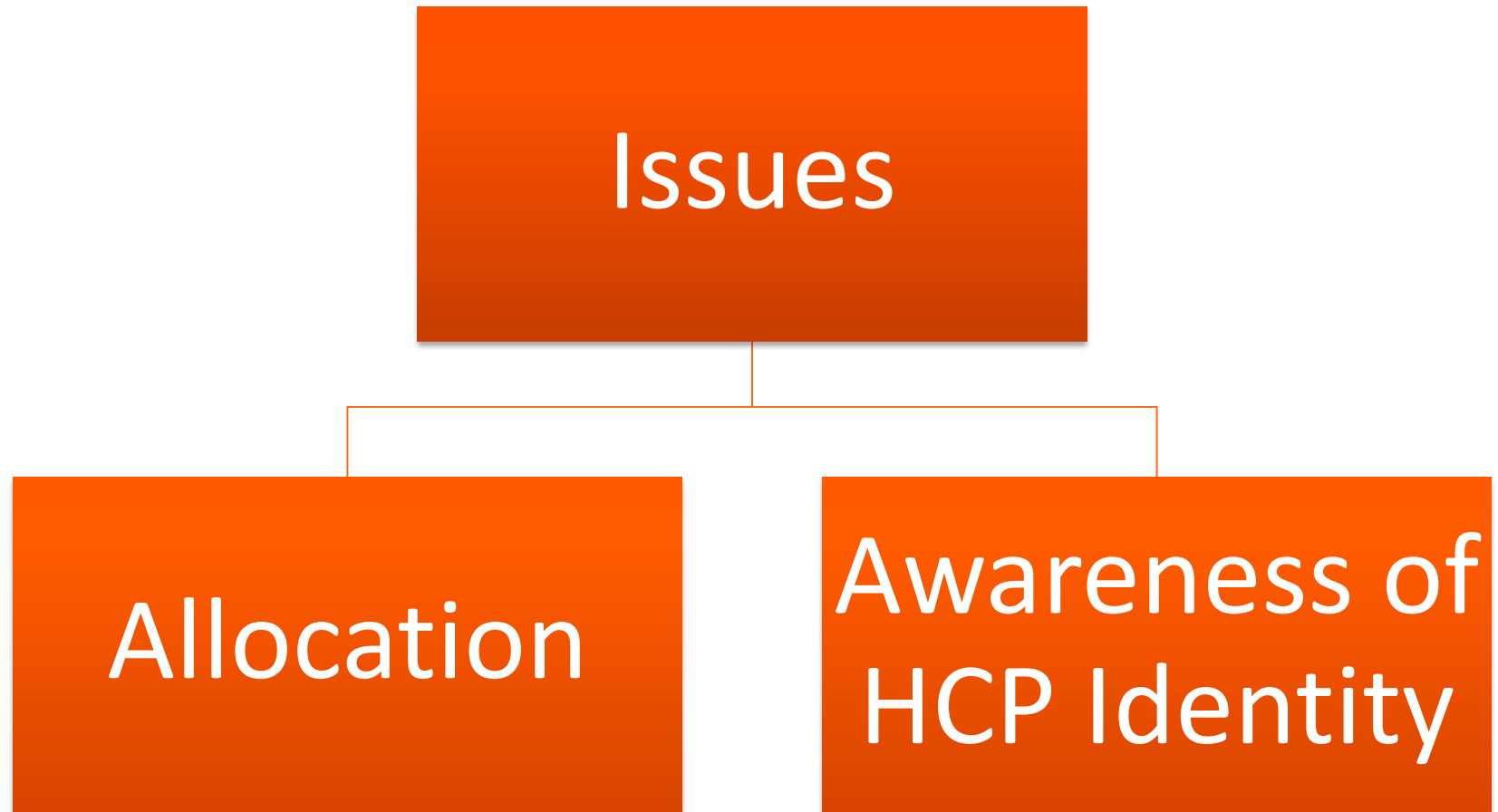
- Appropriate classification
- Reporting of loaner units that have not been retrieved in the 90/120 day time frame
  - Fraud & Abuse/Gift Ban issues
- Fair Market Value (FMV) determination
- Track (and retrieval) of items

- Characterization -- Use Vermont as a basis since it provides the most explanation
  - Demo Unit → Educational item (not returned)
  - Eval Unit → Product used for HCP/patient evaluation (not returned)
  - Loaner Unit → Product used for evaluation (returned)
- Reporting “late” loaners
  - Daily FMV lease rate for each day beyond period
  - Per usage beyond period
- Tracking
  - Electronic system
    - Record delivery on distributor’s tablet
    - Use software to identify number of days loaner; alerts
  - Tracking under federal law may begin in 2012





# GROUP SPEND



# Group Meals

## Federal

- Solo = attribute all spend to physician
- Group = attribute all spend to all physicians (even if not present)
- Do not need to report buffet meals, snacks at conferences/booths

## Massachusetts

- Lunch in office:
  - 5 MDs, 1 Office Staff, 1 Sales Rep.
  - \$315 total bill
- \$315/7 attendees = \$45/per
  - Below \$50 transaction for reporting
  - If reportable, attribute to “an identifiable covered recipient”

## Vermont

- **Front-Office Staff spend:** Attribute all spend to HCPs
- **Multi-Prescriber Practice spend:** Attribute amount of item among all relevant HCPs (i.e., who would use the item). If likely users are unknown, attribute to all HCPs

# Group Meals: Examples of Roll-up Value

- Sales Rep provides \$40 meal in solo practitioner's office

<u>Attendees</u>	<u>Practice</u>	<u>Per Person Value</u>	<u>MA/VT Allocated Value</u>	<u>Fed. Reported Value</u>
Physician	A	\$10	\$13	\$40
Nurse1	A	\$10	\$13	\$0
Nurse2	A	\$10	\$13	\$0
Secretary	A	\$10	\$0	\$0

- Sales Rep provides \$60 meal and there are multiple offices present (affiliations known)

<u>Attendees</u>	<u>Practice</u>	<u>Per Person Value</u>	<u>MA/VT Allocated Value</u>	<u>Fed. Reported Value</u>
Physician1	A	\$10	\$10	\$20
- Nurse 1	A	\$10	\$10	\$0
Physician 2	B	\$10	\$15	\$30
- Nurse 2	B	\$10	\$15	\$0
- Secretary	B	\$10	\$0	\$0
Pharmacist	?	\$10	\$10	\$0

# Conference-related Spend

## Federal

- Statute: Don't report value that is made indirectly to a CR through a 3<sup>rd</sup> party... where the manufacturer is **unaware** of the identity of the CR.
- But see broad 'knowledge standard'

## Massachusetts

- Guidance: Booth snacks are not banned
- Report if transaction is > \$50

## Vermont

- Guidance: Donating items to professional ass'n to be raffled off to HCPs is banned
- Statute: Booth snacks are allowed and aren't reported
- Former Guidance: For CME, report name of grantee, not attendees

- CMS proposes that manufacturer is aware if the manufacturer “has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient.”
  - If a Manufacturer provides a payment through a 3<sup>rd</sup> party to the department chairs at a specific hospital, manufacturer must report because their identities are publicly available
- Consistent with the knowledge standard in many fraud and abuse laws, including FCA
- If agent knows, then manufacturer knows

- Determining when is the company “aware” or “unaware” of HCP identity
  - FCA “knowledge” standard = actual knowledge, deliberate ignorance and reckless disregard (aka should have known)
- Identification of group practice/office members and “relevant prescribers”
- Determining affiliations of non-HCPs/covered recipients
- Lump sum spend (e.g., limo service): equal allocation or individual assignment/opt-out

- Awareness
  - Establish workable policies that provide for consistent treatment of like situations
- Allocation
  - Allow HCPs to opt-out of expense
  - Require Non-HCP names (for auditing), only add HCPs to customer master
  - Divide by the “registered” number of attendees
- Lump sum spend
  - Require itemized expenses, including all attendees & types of spend (e.g., separate food, travel, lodging, fees)
- Identification & Affiliation
  - For relevant prescribers, assign relevant specialties to items and use combination of affiliation data + specialty data to allocate
  - Equal allocation of all unaffiliated non-HCPs
  - Ongoing enhancement of customer master with non-HCP data





# PRODUCT FAMILIES & MULTI- PRODUCT DISTRIBUTORS

# Reporting Product Name

## Federal

- Statute: Report “name of the covered drug, device, biological or medical supply, as applicable.”
- Guidance: Report “[t]he name under which the covered drug, device, biological, or medical supply is marketed. If not available, then [report] ‘scientific name’.”

## Massachusetts

- Product name not required.

## Vermont

- Statute: Report “prescribed products marketed, if any.”
- Guidance: “Identify the type and name of the product or products [up to five] which are associated with the reported expenditure.”
- Private Guidance: Report product name for grants

- Determining what to report
  - Events and other spend may cover a range of products or none at all
  - A “product” may really be a family of related products/SKUs
- Harmonizing the data
  - Contract distributors may carry multiple manufacturer’s products
  - Each manufacturer and distributor may have a slightly different approach

## ■ Product determination

- Use product class or therapeutic area, and provide jurisdiction with list of products that fall within each class or area
- If event not tied to a particular product, request guidance from jurisdiction; use “most popular” product or class/area for VT

## ■ Distributor

- “Preponderance test” – report against the manufacturer whose products accounted for most of the discussion
- Equal across all manufacturers
- Establish contract language and/or guidelines
- Ensure agreement b/t companies so that all amounts are reported, and clearly communicate to distributor

# Partnerships and Other Business Relationships

- Joint ventures and other coop agreements
  - Hypo 1: Company A is a mfgr but Company B is not a mfgr
  - Hypo 2: Company A and B are both mfgrs
- Who reports?

Federal	Massachusetts	Vermont
<ul style="list-style-type: none"><li>• Hypo 1: Not addressed</li><li>• Hypo 2: A or B, but must be in name of which company actually provides the payment, unless agreement requires otherwise<ul style="list-style-type: none"><li>• Only report once</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Hypo 1: Company A</li><li>• Hypo 2: Not addressed</li></ul>	<ul style="list-style-type: none"><li>• Hypo 1: A or B, but in the name of A</li><li>• Hypo 2: A and B are “liable” for reporting, but only 1 must report<ul style="list-style-type: none"><li>• Must be reported in name of “owner”/NDA holder</li></ul></li></ul>

- Issue 1: Who is responsible for tracking and reporting?
  - Manufacturer should always track details on spend conducted on its behalf
  - Review each jurisdiction's rule to determine which company is responsible for *reporting*
- Issue 2: Which manufacturer are you reporting against?
  - Review each jurisdiction's rule to determine which company's name should be included in the report form
- Issue 3: What provisions with partners need to be amended?
  - Agree on which companies are responsible for reporting in which jurisdictions to prevent duplicate or omitted reports
  - Require review of data if report will be submitted in your company's name



Seeing the Forest through the Trees

# **SIGNIFICANCE OF DATA ON MEDICAL DEVICE ENFORCEMENT**

## Sunshine as “Disinfectant”

“I have conducted in the depth [sic] and scope of these relationships between physicians on the one hand, and manufacturers of drugs, biologics, and medical devices on the other hand.

My findings to date are troubling and reveal significant undisclosed financial ties between physicians and industry ...

In this process of what we call transparency, in this process that we call sunshine legislation, I often quote from an opinion of Justice Brandeis, I think in 1914, where he said: ‘Sunlight is the best disinfectant.’”

- *Sen. Charles Grassley, Congressional Record, January 22, 2009.*



# What Disclosure Looks Like

## Top 20 Manufacturers Detail

Rank	Manufacturer Name	Manufacturer ID	Recipient Fullname	City	State	License Type	License Number	Covered Recipient ID	Payment Categories	Number of Events	Total Payment Paid	
	Boston Scientific Corporation	CC0087	Boston Health Care Homeless Program	Boston	MA	Clinic	4LQX	278371	Charitable Donation	2	\$2,000,000.00	
		<b>Total for Covered Recipient : Boston Health Care Homeless Program</b>										<b>\$2,000,000.00</b>
		CC0087	Beth Israel Deaconess Medical Center	Boston	MA	Clinical Laboratory	22D1045854	241789	Compensation for Bona Fide Services	1	\$10,638.00	
									Grants/Educational Gifts	5	\$152,000.00	
									Marketing Studies	1	\$1,844.00	
		<b>Total for Covered Recipient : Beth Israel Deaconess Medical Center</b>										<b>\$164,482.00</b>
		CC0087	Peter L Rosenblatt	Cambridge	MA	Physician	73773	30199	Compensation for Bona Fide Services	29	\$68,497.00	
									Education/Training	1	\$165.00	
		<b>Total for Covered Recipient : Peter L Rosenblatt</b>										<b>\$68,662.00</b>
		CC0087	Massachusetts General Hospital	Boston	MA	Acute Hospital	2168	276130	Marketing Studies	15	\$37,421.00	
		<b>Total for Covered Recipient : Massachusetts General Hospital</b>										<b>\$37,421.00</b>
		CC0087	Douglas K Pleskow	Boston	MA	Physician	54132	27912	Compensation for Bona Fide Services	14	\$22,465.00	
		<b>Total for Covered Recipient : Douglas K Pleskow</b>										<b>\$22,465.00</b>
		CC0087	N.a. Mark Estes III	Boston	MA	Physician	44422	9978	Compensation for Bona Fide Services	1	\$17,500.00	
									Education/Training	2	\$1,741.00	
<b>Total for Covered Recipient : N.a. Mark Estes III</b>										<b>\$19,241.00</b>		
CC0087	Umass Memorial Medical Center Hospital	Worcester	MA	Clinical Laboratory	22D0974724	241108	Grants/Educational Gifts	1	\$1,000.00			
							Marketing	32	\$17,971.00			



Rank	Recipient Fullname	City	State	License Type	License Number	Covered	Manufacturer	Manufacturer	Payment	Number	Total
	Mary Ann Asbell	Cambridge	MA	Physician							
<b>1</b>	<b>Total for Covered Recipient : Mary Ann Asbell</b>										
	Charles M Gibson			Physician							
									Bona Fide Services		
									Food	3	\$334.00
							Ortho-Mcneil Institutional	CC0192	Compensation for Bona Fide Services	1	\$3,900.00
											\$186.65
											\$,328.51
											\$,400.00
											\$315.00
											\$,448.00
											\$,608.00
<b>2</b>	<b>Total for Covered Recipient : Charles M Gibson</b>										
	Stephen John Ferzoco	Wellesley	MA	Physician					Compensation for Bona Fide Services	6	\$194,275.00
											\$17.16
											\$,339.00
											\$,104.00
<b>3</b>	<b>Total for Covered Recipient : Stephen John Ferzoco</b>										
	David M Barrett	Burlington	MA	Physician	160949	2217	Depuy Orthopaedics, Inc.,	CC0135	Compensation for Bona Fide Services	15	\$159,750.00
									Food	2	\$197.00
<b>4</b>	<b>Total for Covered Recipient : David M Barrett</b>										
											\$159,947.00

**Rank**

**1**

Payment Categories	Number of Events	Total Payment
Compensation for Bona Fide Services	6	\$194,275.00

- Health care fraud enforcement is on the rise and the device sector currently is in the crosshairs
- To date, the information that is about to be reported and made public has been confidential.
- Enforcers have needed legal instruments (subpoenas, AID, CIDs, warrants, etc.) to obtain this information



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## DOJ Posts Record For Health Care Fraud Cases


by CARRIE JOHNSON




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*All Things Considered*

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December 30, 2011

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The Justice Department is on track to post a record number of health care fraud prosecutions in 2011. Researchers say DOJ reported 1,235 new cases this year, the largest since they began tracking the crime 20 years ago. U.S. Attorney's Offices in Miami, Puerto Rico and Houston accounted for the biggest number of cases. And DOJ officials say recoveries in these cases are bringing lots of money back to the U.S. Treasury. But some onlookers say the federal government can do more to nip health care fraud in the bud by cutting off payments to fraudulent recipients before they happen.

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