Transparency Reporting

Navigating State, Federal and International Requirements

Carolyn M. Bruguera, Esq.

Principal, IMS Health

March 21, 2016

imshealth™
INTELLIGENCE APPLIED.

Agenda

- Overview of the laws and requirements
  - U.S. Sunshine Act
  - State Laws
  - Global Transparency Requirements
- Q&A

CMS Open Payments

A little “Sunshine” to Brighten Your Day!

2

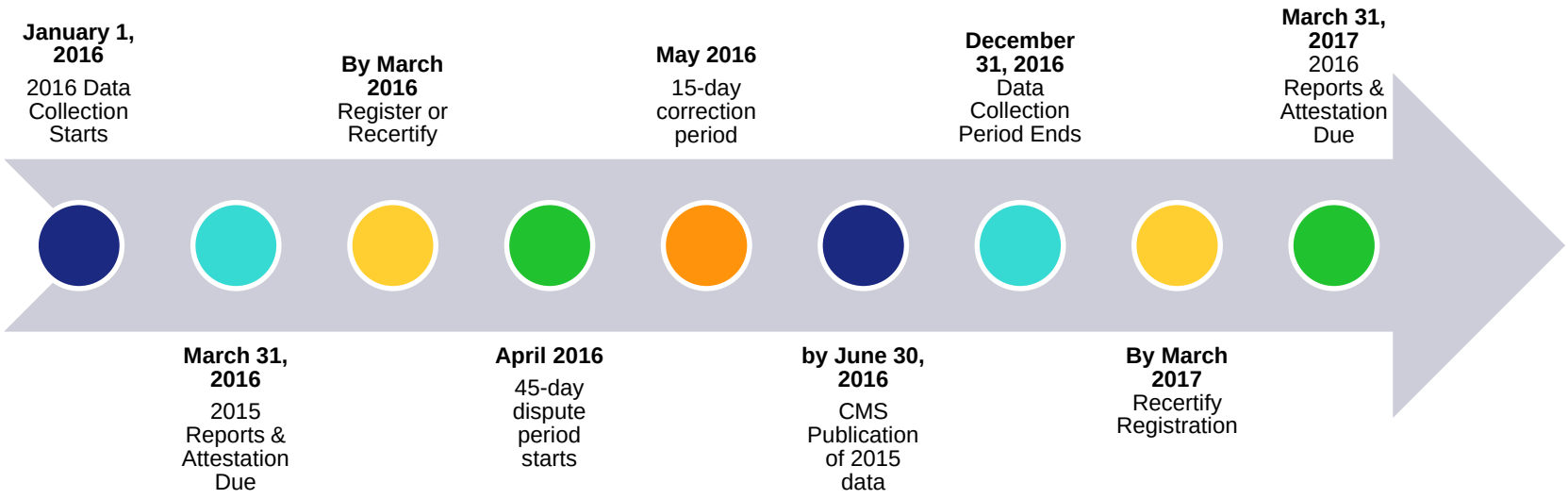
Open Payments: Basics

- The law requires **Applicable Manufacturers** to disclose annually to the Government:
  - any payments or other transfers of value provided to or incurred on behalf of a "**Covered Recipient**" (i.e., physician or teaching hospital);
    - Transactions <$10 do not need to be reported, except when the total amount transferred in a reporting year exceeds $100*; and

    *+*inflation adjustment*
  - physician (or immediate family) ownership in the company.

imshealth™

Open Payments Timeline



imshealth™

Applicable Manufacturers

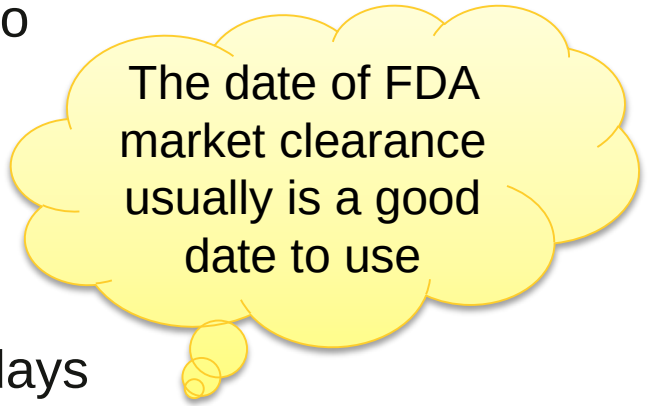
- Manufacturers of covered products, or their affiliated entities, who have U.S. operations
  - Also: distributors who take title to covered products

- "Covered" products are drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid and CHIP
  - **Excluding** OTC products or products that do not require premarket notification or approval
  - **Includes** reimbursable study devices and drugs

Reporting Obligation

- Manufacturers that derive less than 10% of their revenues from covered products do not have to report transfers of value with respect to non-covered products.

- Manufacturers must start collecting data 180 days after one of their products first qualifies as a “covered product”



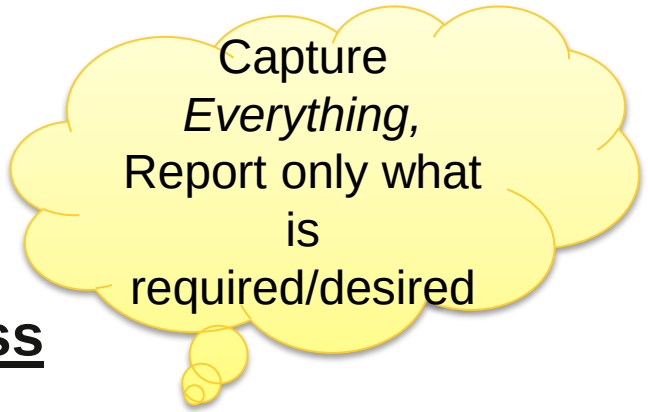
Transfers of Value

- ***Anything of value*** provided directly or indirectly to a covered recipient, or to a third party at the request of a covered recipient

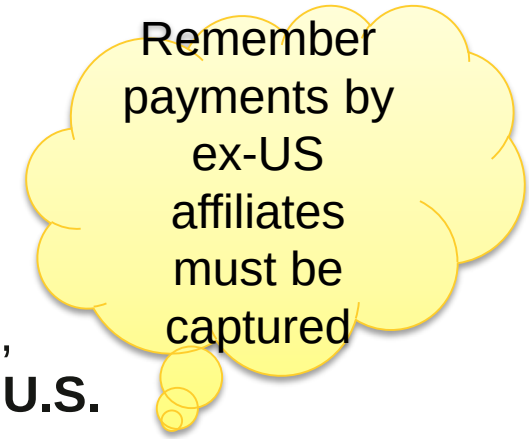
- ***Except:***

  Transfers of less than $10 in value, **unless** the aggregate annual expenditures to the covered recipient exceed $100.

*for 2016 reporting period, these values are inflation-adjusted to $10.22 and $102.19 respectively



Covered Recipients



Physicians and Teaching Hospitals

- Doctors of medicine and osteopathy, dentists, podiatrists, optometrists and chiropractors who are **licensed in any U.S. state.**
  - Excludes medical residents

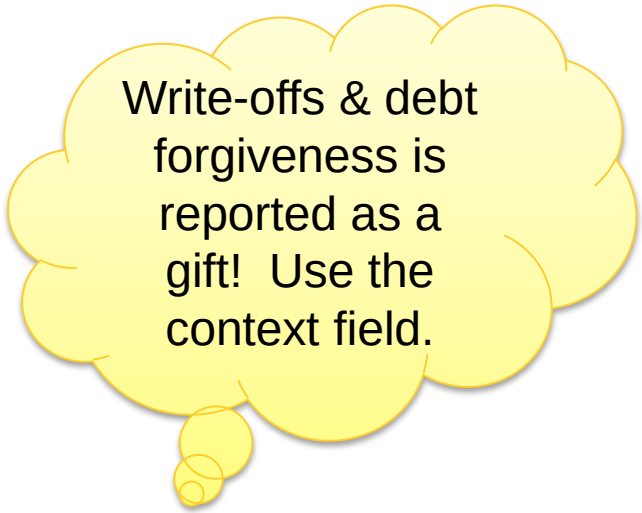
- Hospitals that receive direct and indirect Medicare Graduate Medical Education funds (GME, IME and psychiatric IME)
  - List of "teaching hospitals" posted on CMS website

Information Reported

- Name and Primary Business Address
- For Physicians: Specialty, NPI (if applicable),license number, state of license. (For teaching hospitals: EIN)
- Dates and amounts of payments
- Form of payment
  - Cash or cash equivalent
  - In-kind items or services
  - Stock or stock options
  - Dividend, profit, or return on investment
- “Nature of Payment”
- Product(s) to which payment relates (if applicable)

Nature of Payment

- Consulting
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel (including destination)
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty for a medical education program
- Grant



Research Payments

- Transfers of value related to research that are made pursuant to a **written agreement or protocol** are reported on a separate template that includes information about the clinical trial.

- If payment relates to pre-market R&D, publication can be delayed until earlier of FDA approval/clearance or 4 years.

Special Circumstances

- If a manufacturer “requires, instructs, directs, or otherwise causes payment” a third party to make a transfer of value to a covered recipient, the manufacturer must report the payment to the third party and identify the indirect covered recipient.
- if payment is to a physician owner/investor this must be noted in the report
- **Ownership Reports**:
  - In addition to general and research payment reports, companies must submit a report of all ownership interests held by physicians and/or their immediate family members (excludes publicly-held securities and unknown investors)

Exceptions from Reporting

- Product samples for patient use (includes coupons or vouchers)
- Evaluation products, not to exceed 90 days (i.e., 90-day supply of disposable devices, or 90-day equipment loan)
- Educational materials or items that **directly benefit patients** or are for **use with patients**
- In-kind items to be used for charity care
- Discounts and rebates
- Services and replacement items provided under a warranty or services contract

13

Exceptions from Reporting

- Indirect payments, if the manufacturer does not know the identity of the recipient
- Buffet meals, beverages and snacks offered at “a large-scale conference or similar large-scale event.”
- Transfers of value of less than $10 each at a “large scale conference or similar largescale event” or events open to the general public*
- Through 2016 Reporting Year: Indirect payments for speaker fees, if the meeting is accredited, and the manufacturer does not select the speaker or provide a list of suggested speakers

14

Exceptions from Reporting

- Transfers of value by manufacturers to employees who are physicians
- Transfers of value made solely in the context of a personal, non-business-related relationship
- Transfers of value to research subjects who are patients or research subjects not acting in their professional capacity
- Fees paid by a manufacturer that self-insures, for its employees' healthcare
- Expert Witness Fees

15

Recent Developments

- Effective for reports filed in 2017:
  - Exclusion for speaker payments at accredited CME event has been eliminated; and
  - CMS will require the reporting of the marketed name of the related covered and non-covered drugs, devices, biologicals, or medical supplies
  - Stock, stock options, other ownership interests must be reported as distinct forms of payment

16

Federal Preemption

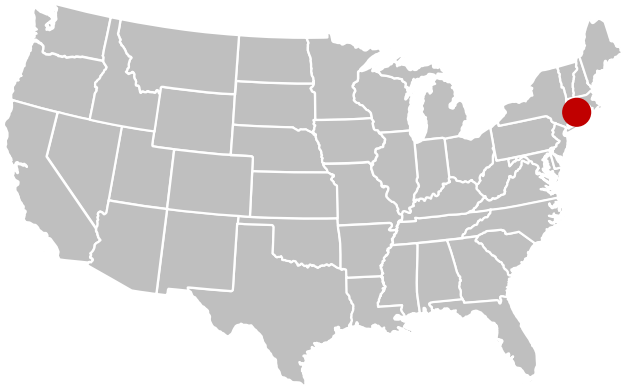
- State and local governments may require reporting of information other than what is required by Open Payments
  - Transfers of value excluded by the law except for the $10/$100 exclusion
  - Additional covered recipients (e.g., Massachusetts and Vermont require reporting of interactions with pharmacists)
  - Indirect payments by a third party where the manufacturer does not know the identity of the covered recipient is not included in the definition of “transfer of value” (e.g., blinded research)
    - D.C., Massachusetts and Vermont exclude from disclosure certain types of “double-blinded” research

17

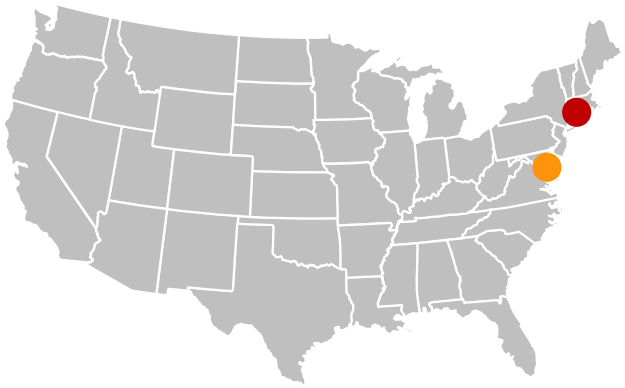
What's New?
State Update

imshealth™

Connecticut

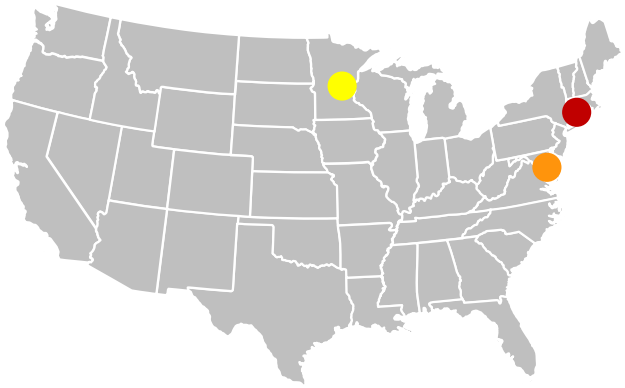


- Law requires manufacturers to report ToVs to advanced practice nurses.
  - If practice “not in collaboration with physician”
  - Tracking of payments started 1/1/16
  - First report due July 1, 2017 and annually thereafter
- The same information as required by federal law for physicians and teaching hospitals
- CMPs of $1,000 to $4,000 for each payment not reported
- List of covered APRNs posted annually on CT DPH website



District of Columbia

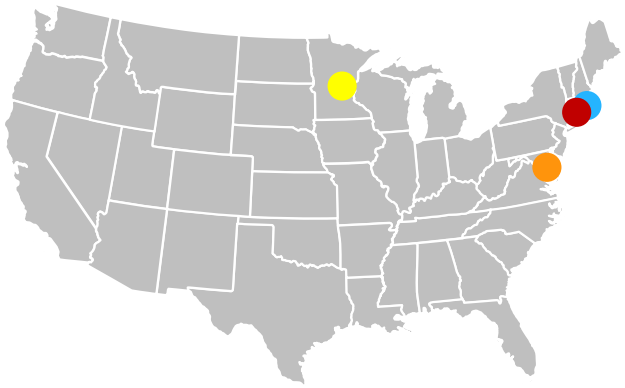
- Pharmaceutical manufacturers and labelers must report certain marketing expenditures in the District
- Includes educational, marketing and travel expenses
- Also includes all food, entertainment and gifts of $25 or more
- Covered recipients are: individuals and entities authorized to provide healthcare in the District (including employees of providers).
- Reports due annually by July 1 along with payment of $5,000 fee.



Minnesota

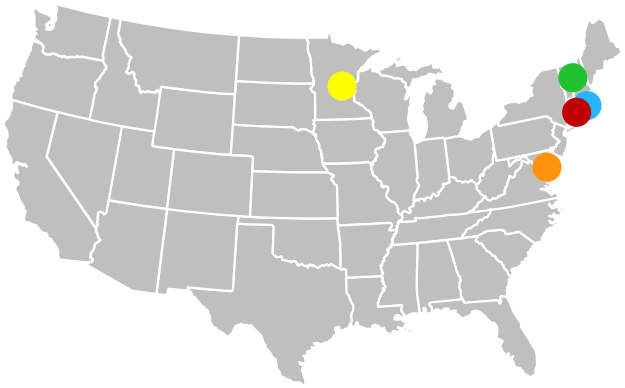
- Pharmaceutical manufacturers and wholesalers must report payments to practitioners
- Includes **registered nurses, physician assistants, veterinarians and dental therapists**
- Reporting threshold of $100 in annual aggregate per practitioner
- Annual reports submitted to Board of Pharmacy by May 1 of following year.

Massachusetts



- Requires pharmaceutical and medical device manufacturers to report transfers of value to prescribers and their employees
- $50 reporting threshold
- Annual reports due July 1 of subsequent year; registration and fee due in August.
- In late 2012, DPH issued regulations requiring quarterly reports related to non-CME educational presentations at which meals or refreshments are provided
- Still awaiting regulations and guidance; preemption questions.

Vermont



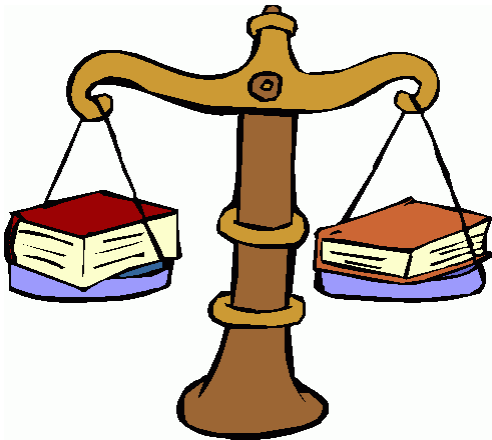
- Applies to transfers of value by pharmaceutical and medical device manufacturers to Vermont health care prescribers and their employees as well as patient and physician organizations and universities.
- Annual reports to VT AG's office due April 1 of subsequent year
- $25 reporting threshold
  - "Alternative aggregate disclosure" for educational items
- See VT AG's Office publications (Prescribed Products Guide), which clarifies how to report:
- Active enforcement; penalties imposed

Global Transparency Reporting

24

Overview of Global Transparency: *Types of Rules*

- Laws vs. Industry Codes
  - ***Law***: system of rules that a government recognizes as regulating the actions of its covered parties
    - Generally, the rules are not voluntary
  - ***Industry Code***: system of rules that a non-govermental group adopts to regulate the actions of its members
    - Self-Regulation (companies typically join voluntarily)
  - Enforcement may apply to both types of rules



25

Snapshot of Reporting Requirements

Country	Industry Code	Law	Pharma	Med Device
Australia	X		X	
Belgium	x		x	x
Denmark	X	X	X	X
Estonia	X	X	X	
EFPIA*	X		X	
France		X	X	X
Germany	x		x	
Greece	x		x	
Hungary	X		X	
Japan	X		X	X
Mexico	x		x	
Netherlands	X		X	X
Portugal	X	X	X	
Slovakia	X	X	X	X
United Kingdom	X		X	
United States		x	x	x

EFPIA: Overview

- European Federation of Pharmaceutical Industries and Associations
- Applies to 39 companies and 33 European countries for which there is an EFPIA Member Association

EFPIA: Reporting

- Reporting requirements contained in 2 codes:
  - EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations
    - “HCP/HCO Disclosure Code”
  - EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations
    - “PO Code”

28

EFPIA: What's reported

- *HCP/HCO Disclosure Code*:
  - Direct and indirect transfers of value… in connection with the development and sale of prescription-only Medicinal Products exclusively for human use.
- *PO Code*:
  - Financial support and/or significant indirect/non-financial support provided to patient organisations.
  - Transfers of value provided to patient organisations that are engaged to provide significant contracted services.

29

EFPIA: What's *not* reported

- *HCP/HCO Disclosure Code*: Transfers of Value that are:
  - solely related to OTC medicines
  - educational materials
  - certain meals and drinks
  - medical samples
  - part of ordinary course purchases and sales of Medicinal Products

30

EFPIA: HCP/O Report Template

SCHEDULE 2 - TEMPLATE

Date of publication: .....

	Full Name (Art. 1.01)	**HCPs:** City of Principal Practice **HCOs:** city where registered (Art. 3)	Country of Principal Practice (Schedule 1)	Principal Practice Address (Art. 3)	Unique country identifier *OPTIONAL* (Art. 3)	Donations and Grants to HCOs *(Art. 3.01.1.a)*	Contribution to costs of Events *(Art. 3.01.1.b & 3.01.2.a)*		Fee for service and consultancy *(Art. 3.01.1.c & 3.01.2.c)*			**TOTAL** *OPTIONAL*
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	
HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP*** *(i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*											
	Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	
	Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	
	etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Optional*
	Number of Recipients in aggregate disclosure - *Art. 3.02*					N/A	N/A	*number*	*number*	*number*	*number*	*Optional*
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - *Art. 3.02*					N/A	N/A	%	%	%	%	N/A
HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO*** *(i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*											
	HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Optional*
	HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Optional*
	etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Optional*
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Optional*
	Number of Recipients in aggregate disclosure - *Art. 3.02*					*number*	*number*	*number*	*number*	*number*	*number*	*Optional*
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - *Art. 3.02*					%	%	%	%	%	%	N/A

	AGGREGATE DISCLOSURE		
R &D	Transfers of Value re Research & Development as defined - *Article 3.04 and Schedule 1*	*TOTAL AMOUNT*	*OPTIONAL*

latest update: 11 December 2013 v1

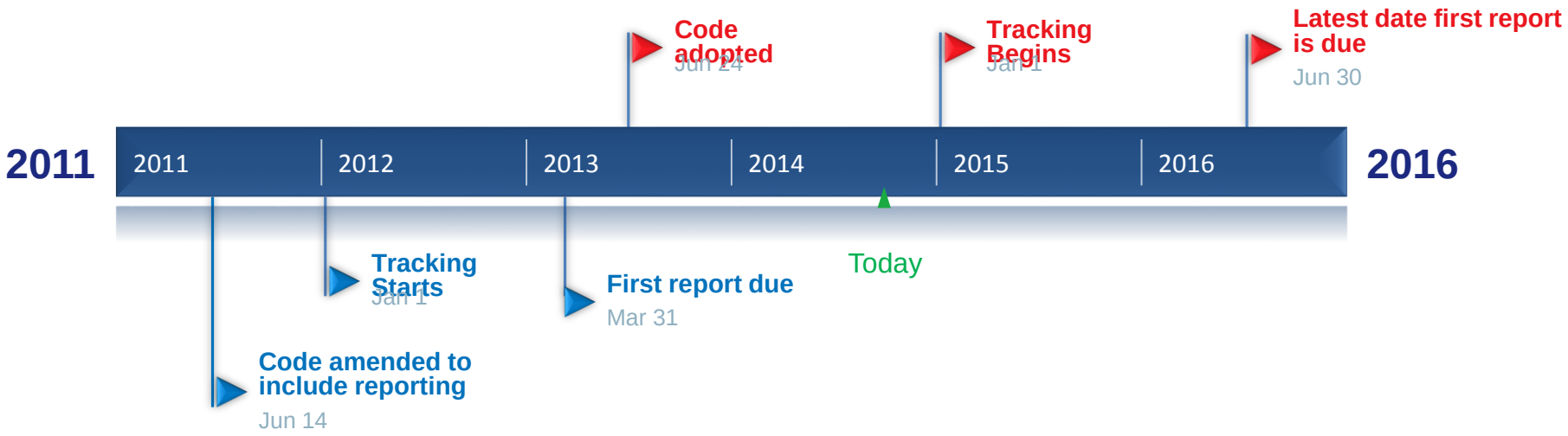
31

EFPIA: Timeline

LEGEND

HCP/HCO Disclosure Code

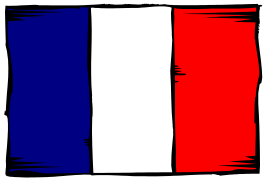
PO Code



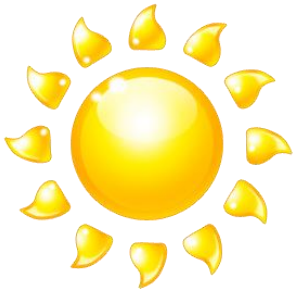
32

EFPIA: Recent Developments

- Transposition of the HCP/HCO Disclosure Code into the Member Association codes
  - Deadline for transposition was December 31, 2013
  - By March 31, 2014 the EFPIA Codes Committee was required to produce a report on the transposition "so as to allow sufficient time to remedy inadequate or incomplete transposition by any Member Association" prior to the June 2014 General Assembly meeting.



France - Loi Bertrand



- May 2013 – regulations published
- August 2013 first reports submitted to to professional *ordres*
- October 2013 publication on ordre and company websites
- February 2014 – reports to government-run website
- June 2014 – government website opened to public

www.transparence.sante.gouv.fr

February 2015 – conseil d'etat decision invalidates exclusion for fees for service

December 2015 – amendment includes fees for service

February 2016 – second half 2015 reports filed; no new implementing decree

Who must report?

- Any company that **manufactures** or **markets** regulated health products in France
  - includes **drugs, medical devices**, and **biologics**
  - **regardless** of whether government reimbursement is available
- Any company **providing services** related to the manufacture and sale of regulated health products or **acting on behalf of manufacturers and distributors** of covered products

What has to be disclosed?

Contracts ("conventions")

The **"existence and nature"** of all contracts with health care providers, including

- Research agreements
- Consulting Agreements
- Grants Agreements
- Hospitality Agreements

Benefits ("avantages")

All **benefits** (transfers of value) **in excess of 10 euros**, including

- Gifts
- Meals
- Travel support
- Cash payments

36

Covered recipients

- health care professionals
- students for health professions
- medical institutions, clinics
- training institutions
- physician organizations
- learned societies and foundations
- medical institutions
- publishers
- certain consultants (e.g. CROs)

Exceptions

Commercial contracts for the **sale of goods and services by covered companies** are excluded from the disclosure requirement.

Under the initial implementing decree **fees paid to health care providers for services rendered** were not treated “benefits” requiring disclosure

- However, this does not limit the requirement to disclose the “existence and nature” of the contract pursuant to which the services are rendered.
- 2015 court decision and amendment invalidated this exclusion
- February 2016: awaiting implementing decree for reporting fees for service

Reporting under the *Loi Bertrand*

Reports due every six months

- August 1 for Jan-June of same year
- February 1 for Aug – Dec of prior year

Contracts reported *15 days* after execution

Electronic Upload to transparency website maintained by Ministry of Health and Social Affairs

Publication on Website April 1 and October 1

Data Privacy - EFPIA

National Codes must follow EFPIA disclosure rules, except to the extent required to comply with local law

- Could require consent of HCP
  - What if consent is revoked?
- Could require keeping information public for a shorter period than three years, or keeping backup documentation shorter than 5 years

Pending Data Protection Reforms

- Single European law for data protection, replacing the current inconsistent patchwork of 28 national laws. One single supervisory authority (not 28)
- Companies based outside of Europe will have to apply the same rules and will be subject to enforcement by European regulators.
  - Fines of up to 2% of global annual revenues

What does this mean for US-based manufacturers?

- OUS affiliates must comply with local law when transferring or processing personal data
- Transfers to US *prohibited* unless
  - Privacy Shield implemented*, or
  - Appropriate intercompany agreements or BCRs are in effect, or
  - HCP consents (subject to revocation rights)
- Monitor pending rule changes

*Safe harbor invalidated in 2015, Privacy Shield framework pending

42

Parting Thought

Be Able to Defend Your Spend

Know Your Data Before “They” Do

&

Use data to evaluate your Compliance Program effectiveness

imshealth™

Who will Mine the Data & Why?

- States
  - State gift ban & disclosure
  - Consumer Protection
  - Pricing
- CMS
  - Open Payments Violations
  - Utilization
- OIG/MFCU
  - Anti-kickback
  - Exclusion
- FDA
  - Disclosure of conflicts
- NIH
  - Research grants/conflicts
- IRS (and ex-spouses)
  - Undisclosed income
- Whistleblowers
- Media
- Hospitals
  - COI
  - Med Staff By-laws
  - Employed docs
- Vendor Credentialing Firms
  - New access requirement
- Health Plans
  - Participation Agreement compliance
  - Utilization
  - COI
- Group Practices
  - Undisclosed income / relationships
- Physicians
  - Accuracy
  - Total and hourly rates
- Plaintiff Counsel
  - Product liability
- Foreign governments and trade associations / societies
- Your competitors

Q&A

45

ACME, INC.

2016 Advisory Board Meeting – London, UK

Transparency Hypothetical

imshealth™
INTELLIGENCE APPLIED.

ACME, Inc. is a medical device manufacturer with its headquarters in Sunnyvale, California. Company A's European operations are managed by its subsidiary, ACME BV, which is headquartered in the Netherlands. ACME sells products directly in the Netherlands and through distributors in the rest of Europe. Company A's products are used in a medical procedure that is reimbursed by Medicare and Medicaid and reimbursement is pending in Europe.

ACME has organized an advisory board meeting in London to be held in March, 2016. ACME has invited the following HCPs to attend:

3 physicians from the US (California, Nevada, Massachusetts)
2 physicians from Europe (Germany, Belgium)
1 nurse practitioner from the US (Minnesota)
1 nurse practitioner from Europe (France)

ACME March 2016 Advisory Board Meeting

ACME, Inc. enters written agreements with each HCP agreeing to pay a fee for their participation, and to arrange their travel to the meeting.

ACME, Inc. books flights for all of the US-based HCPs. ACME BV books trains or flights for the Europe-based HCPs. ACME BV also books hotel rooms for all 7 HCPs, and arranges meals during the meeting.

ACME, Inc.'s VP of Marketing attends the meeting and presents each HCP with a plaque commemorating his or her participation.

Following the meeting, ACME, Inc. will pay each attendee an honorarium of $1,000 by check or wire transfer. The California physician has requested that his payment be made to a charity he supports, and the Nevada physician has requested that her payment be made to her practice group.

Questions

1. Which payments are reportable?
2. Who has the obligation to report them?
3. Are any of the payments not reported? If not, why?
4. What if ACME is a pharmaceutical manufacturer?

Analyzing Reporting Obligations

Is the company covered by the law or code?

- -territorial limits of law?
- -type of manufacturer (e.g. device, drug, medical supply, biological)?
- -is reimbursement status relevant?
- -affiliated entities covered?
- -who has the reporting obligation?
- -industry codes: membership in trade group?

Is the recipient covered?

-physicians vs. other HCPs
-hospitals vs. other types of entities
-licensure and place of practice

Is the payment a reportable payment?

-exceptions and reporting thresholds
-indirect and third-party payments
-preemption