PRESENTER

- Pat Schaumann, CMP, CSEP, DMCP, HMCC
- Director, Professional Development-Healthcare Sector
- MPI
- Author, "*Breaking the Code to Healthcare Compliance*" *1st and 2nd Edition*

OUR PANEL OF EXPERTS

Jenna Ford
Senior Manager, Transparency & Aggregate Spend Operations
Genentech

Dana Marshall, CMP, CMM
Principal
Meetings Defined

Bonnie Weiss, HMCC
Director, Global Pharmaceutical Sales-Americas
Hyatt Hotels Corp.

WHAT?

HISTORY

- Introduced by Senators Grassley (IA) and Kohl (WI) to be included in the 2010 Patient Protection and Affordable Care Act
- The law requires all manufactures drugs, devices, biologics, and medical supplies to annually report to the Centers for Medicare and Medicaid Services (CMS) the aggregate spend and other transfers of value to physicians and teaching hospitals.

WHY?

SHEDDING LIGHT

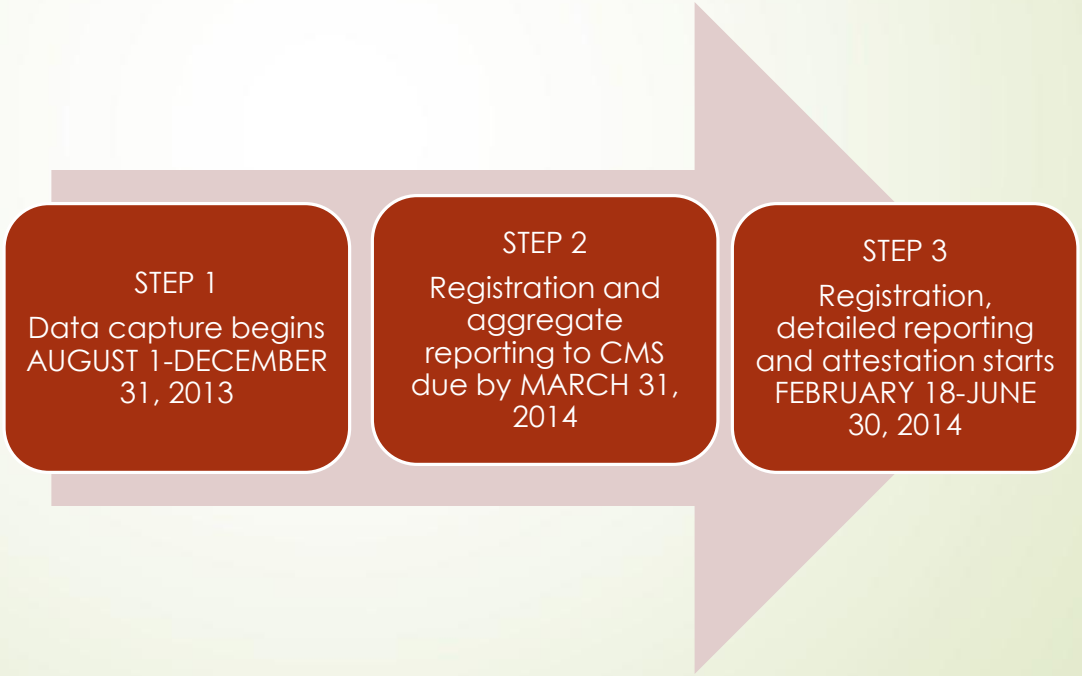
- The transparency provisions would shed light on the full range of financial interactions between manufacturers of drug or device products, and the doctors or teaching hospitals.
- Those interactions can undermine good prescribing, patient trust in doctors and affordable care.

MORE LIGHT

- Influence over product endorsement.
- Concern that manufacturers' influence over physician education may skew the information physicians receive.

WHEN?

TIMELINE OF EVENTS



TIMELINE OF EVENTS

STEP 4

Physician and Teaching Hospital Open Registration

JUNE-AUGUST 9, 2014

STEP 5

Review and dispute (45 days) JULY 14-AUGUST 2, 2014

STEP 6

Correction Period (15 days) SEPTEMBER 9-SEPTEMBER 23, 2014

PUBLIC ACCESS TO DATA

CMS posted payments or other transfers of value and ownership or investment interest reports on a public website for the:

- Initial implementation year (partial reporting year) no later than **September 30, 2014**
- On-going implementation years on June 30 each year after the implementation year.

2015 REPORTING CYCLE

CMS Reporting Site down until 2/2/2015

Manufacturers will have from 2/1/15-3/31/15 to collect and submit data

April-May 2015- Physicians & Teaching Hospitals Review & Dispute (45 days)

May-June 2015 - Manufacutres & GPO's Review & Correct Data

June 30 2015 - Data Displayed to Public on Open Payments Website

WHO?

WHO IS REQUIRED TO REPORT

- **Applicable Manufacturer** - an entity may be deemed a manufacturer if the entity is engaged in production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution, an entity may also be considered a manufacturer and subject to the Sunshine Act reporting requirements if it is "under common ownership" with a traditional manufacturer.

ALSO…

- Group Purchasing Organizations (GPO's)
- Physician Owned Distributorships (POD's)

COVERED RECIPIENTS

- Open Payments requires appropriate manufacturers to annually report certain payments or transfers of value provided to ***physicians or teaching hospitals***, known as covered recipients.

- Medical Doctors (MD)
- Doctors of Optometry (OD)
- Doctors of Osteopathy (DO)
- Doctors of Dental Surgery and Doctors of Dental Medicine (DDS, DMD)
- Doctors of Podiatry (DPM)
- Doctors of Chiropractic Medicine (DC)

WHAT TO REPORT?

REPORTING ON…..

1. Reports from applicable manufacturers on payments or other ***transfers of value*** to covered recipients

2. Reports from applicable manufacturers and applicable GPOs and PODs concerning ownership and investment interests of physicians and their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors.

   - **Form of Payment**

     Cash or cash equivalent

     In-kind items or services

     Stock, a stock option, or any other ownership interest

WHAT TO REPORT

- **Name**
- **Business Address**
  - Physicians – use primary practice location
  - Teaching Hospitals – Use address included in the CMS list
  - Physician specialty
  - National Provider Identifier (NPI number)
  - Date of payment (date upon which payment or transfer of value was provided

WHAT TO REPORT?

- **NATURE OF PAYMENT**
  - Consulting fees
  - Research
  - Compensation for services other than consulting
  - Charitable contribution
  - Honoraria
  - Current or prospective
  - Gift
  - Ownership or investment interest
  - Entertainment

NATURE OF PAYMENT CONT..

- Food
- Direct compensation for serving as faculty or as a speaker for a medical education program
- Travel (including specified destinations)
- Education
- Grant

WHAT TO REPORT?

- Food
- Allocate the cost of meal to any covered recipient that could potentially partake in the meal
  - *Example - $25 worth of bagels is brought to a solo physician's office. The physician does not eat the meal, but his staff does. $25 would be reported under the physician's name.*
- Direct compensation for serving as faculty or as a speaker for a medical education program
  - *Include all speaker payments, not only those related to "medical education programs"*

WHAT IS EXCLUDED?

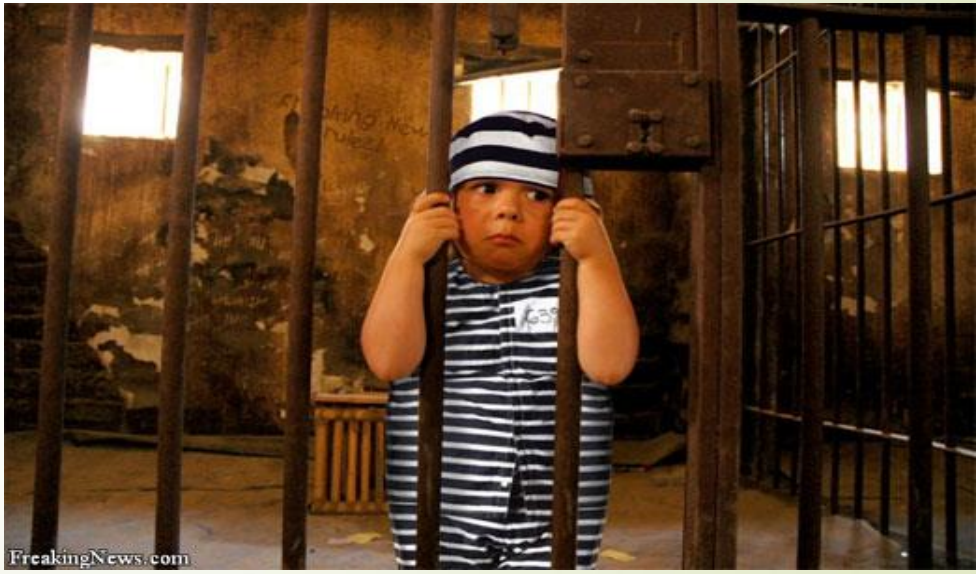
- **Payments less than $10**
  - If $100 threshold exceeded for the Covered Recipient in one year, then must report the total of all small payments provided to a covered recipient, aggregated by nature.
  - *Example: In one year, a Covered Recipient receives five meals, each worth $9; speaker fee of $150; $5 worth of pens – grand total is $200, so company has to report*
    - *$150 speaker fee as Direct Compensation*
    - *$5 for pens as Gift*
    - *$45 for meals as Food*

    Educational Materials

    Limited to "materials" (i.e. pamphlet) that directly benefit patients

    CMS will consider including materials intended to educate covered recipients (i.e. medical textbook)

PENALTIES



VIOLATIONS

- **CONSIDERATIONS-**authorizes the imposition of civil monetary penalties (CMP) for failure to report the required information on a timely basis in accordance with the law.
  - At lease $1,000, but no more than $10,000, for each payment or other transfer of value, or ownership or investment interest not reported.
  - The maximum CMP with respect to each annual submission for failure to report is $150,000.
  - For knowing failure to submit required information in a timely manner, CMPs will range between $10,000 and $100,000 for each payment that is not reported.
  - The maximum CMP for knowing failure to report timely, accurate and complete information is $1 million for each annual submission.
  - Audits
    - CMS reserves the right to audit
    - Manufacturers must maintain records for 5 years from date of the payment was published publicly

IMPACTFUL UPDATES

CMS PAYMENT UPDATE

- On August 10, 2014 a problem with the CMS' Open Payments transparency program registration system led CMS to temporarily disable the physician portal.
- CMS deleted the exception of accredited CME Speaker programs saying the clause was redundant.
- CMS changed an exception for Medical Device reporting.
- CMS is standing by the September 30, 2014 posting for disclosure to the public any payments made from August 1, 2013 to December 31, 2013.

FIRST REPORTING CYCLE RESULTS

Total Number of Physician is the U.S. – 546,000

Total Number of Physician Who Registered in the Open Payments System – 26,000

Total Number of Teaching Hospitals in the U.S. – 1,100

400 Teaching Hospitals Registered in the Open Payments System

REPORTING RESULTS

- Total Number of Records Submitted by Manufacturers
  - 4.4 Million
- Total Value
  - $3.5 Billion
- Total Number of Reporting Applicable Manufactures and GPO's
  - 1,419

About 40% of the records published today are de-identified.

MORE REPORTING RESULTS

OPEN PAYMENTS DATA NOT PUBLISHED ON 9/30/2014

Reason 1

Unresolved disputes at the end of review period

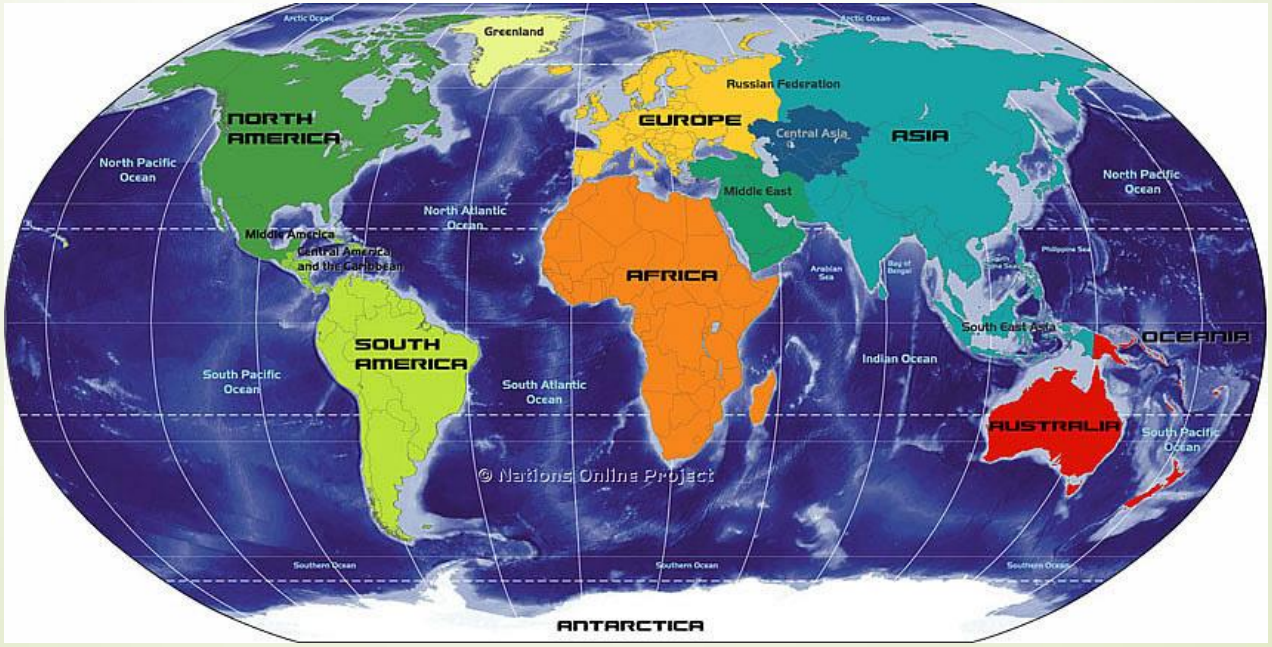
- Value of Records $514 Million
- Number of Records 9,000

Reason 2

Delay in Publication

- Value of Records $551 Million
- Number of Records 190,000

GLOBAL EFFECTS ON REPORTING



UNITED STATES

PREEMPTION OF STATE LAWS

- California
- Connecticut
- Louisiana
- Massachusetts
- Minnesota
- Nevada
- Vermont
- Washington, D.C.
- West Virginia

EUROPE

EFPIA (European Federation of Pharmaceutical Industries new Disclosure Code

- 33 Country members

ASIA-PACIFIC
INDIA
LATIN AMERICA
OTHER

WHAT DOES ALL OF THIS MEAN TO PLANNERS AND SUPPLIERS WORKING WITH HCP'S?

According to Donn Herring, leading healthcare attorney and partner with Lathrop & Gage…

- *From a legal standpoint, a planner would not have direct responsibility to the government or its various regulatory entities for the actions it takes in planning and providing a meeting/event for a medical device/pharmaceutical company. These obligations rest directly on the company and cannot simply be passed-off to the planner.*

MORE…

- One other thing to keep in mind, the rules in this area are far from uniform and are interpreted and implemented very differently from one medical device/pharmaceutical company to another. As a result, a planner should obtain from the company the exact rules and guidelines it expects to be followed in connection with a meeting/event so the planner will know its exact obligations with respect to expenditures and the reporting thereof.

TRENDS AND CHANGES IN THE MEETING INDUSTRY

- Booking lead times in medical meetings globally continue to shrink
- Short-turnaround bookings
  - International effect
- Room caps
- Food and beverage caps
- Hotel rates up 4.5% in 2015
- Airfares increase – 3%
- Europe could be a bargain – 0.1% increase (not U.K.)
- Social technology use continues to rise – FDA watching
- Compliance is a concern shared across industries and countries
- Funding challenges

HELPFUL REMINDERS - MPI

- Healthcare Meeting Compliance Certificate program (HMCC)
- Educational Events
- CIC – CMP-HC

- *"Breaking the Code to Healthcare Compliance-Meeting Professionals Edition" by Pat Schaumann, released in late summer, 2013*

Q & A