Conflicts of Interest

What happens when what is reported to you does not match what is reported by or to others.

HCCA Compliance Institute
April 22, 2013
Session 111

Marti Arvin,  
Chief Compliance Officer, UCLA Health System

Leon Goldman, MD  
Chief Privacy Officer, Kyruus, Inc.

• How does PPSA change the ‘playing field’
• Challenge of growing volume of data in healthcare.
• Challenge of relying on disclosure for monitoring physician-industry interactions.
• Challenge of public data about physicians.
  – There is more out there than you may realize.
• Moving from disclosure based to verification based processes.
  – Using data to engage physicians and preserve industry-physician relationships that are of value.
Effect of PPSA

- The PPSA will make managing conflict of interest much easier: 2%
- The PPSA will make managing conflict of interest somewhat easier: 30%
- The PPSA will have no effect on managing conflict of interest: 2%
- The PPSA will make managing conflict of interest somewhat more difficult: 34%
- The PPSA will make managing conflict of interest much more difficult: 26%
- Don't know/Unsure: 0%

From AHA Solutions © 2013

Where we get data

- State medical boards (all 50 states)
- Hospital and practice group websites
- Publication repositories (i.e. PubMed)
- CMS NPI database
- CMS patient sharing graph
- Federal sanction databases (i.e. OIG, GSA, FDA)
- Secretary of State corporation databases (in states where publicly or commercially available)
- CMS Hospital Compare, CMS Physician Compare
- HealthData.gov
- Clinical trial registries (i.e. ClinicalTrials.gov)
- Grant registries (i.e. NIH RePORTER)
- Life science manufacturer corporate websites

Each data source is updated at different frequencies dictated by the actual frequency of updates of the sources themselves.
## What can be found today

### Provider Demographic Data

<table>
<thead>
<tr>
<th>Practice Affiliation(s)</th>
<th>State Licensure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialties</td>
<td>Board Certifications</td>
</tr>
<tr>
<td>Medical School / Training</td>
<td>Photos</td>
</tr>
</tbody>
</table>

### Industry Interactions

<table>
<thead>
<tr>
<th>Company payments</th>
<th>Sponsored research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry rel. disclosures</td>
<td>Company director positions</td>
</tr>
<tr>
<td>Self-reported disclosures</td>
<td></td>
</tr>
</tbody>
</table>

---

## What can be found today

### Legal Records

<table>
<thead>
<tr>
<th>Malpractice payments</th>
<th>Hospital disciplinary records</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA debarment list</td>
<td>FDA restriction lists</td>
</tr>
<tr>
<td>State disciplinary records</td>
<td>OIG exclusions</td>
</tr>
</tbody>
</table>

### Professional Activity Data

<table>
<thead>
<tr>
<th>Publications</th>
<th>CME teaching</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trials</td>
<td>Professional society memberships</td>
</tr>
<tr>
<td>Conference talks</td>
<td>Grant awards</td>
</tr>
<tr>
<td>Guidelines committees</td>
<td>Patents</td>
</tr>
</tbody>
</table>
Example of a Big Data Problem: Health Care Provider (HCP) Name Disambiguation

Over 50% of healthcare providers see two or more versions of their name across publicly-available databases.

Dealing with messy data

Currently 2,500 different payment types

157 different ways to say 'honoraria':
{Honoraria, Honoraria and Expenses for Speaking, Speakers Bureau/Honoraria, Meeting Speaker Honoraria, Consultant Fees/ Honoraria, Reasonable honoraria, ...}
Is this one person? Two people? Three?

<table>
<thead>
<tr>
<th>Name / Payee</th>
<th>City</th>
<th>State</th>
<th>Company</th>
<th>Period</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claus, Santa</td>
<td>BOSTON</td>
<td>Mass.</td>
<td>Eli Lilly</td>
<td>2011 Q1</td>
<td>Travel</td>
</tr>
<tr>
<td>Claus, Santa / Clinical Research Institute, LLC</td>
<td>Natick</td>
<td>Mass.</td>
<td>Eli Lilly</td>
<td>2011 Q1</td>
<td>Consulting</td>
</tr>
<tr>
<td>Claus, Santa / Clinical Research Institute, LLC</td>
<td>Natick</td>
<td>Mass.</td>
<td>Eli Lilly</td>
<td>2011 Q1</td>
<td>Speaking</td>
</tr>
<tr>
<td>Claus, Santa M</td>
<td>Natick</td>
<td>Mass.</td>
<td>Eli Lilly</td>
<td>2010 Q1-Q4</td>
<td>Travel</td>
</tr>
<tr>
<td>Claus, Santa M / Clinical Research Institute, LLC</td>
<td>Natick</td>
<td>Mass.</td>
<td>Eli Lilly</td>
<td>2010 Q1-Q4</td>
<td>Consulting</td>
</tr>
<tr>
<td>Claus, S. M. / Clinical Research Institute, LLC</td>
<td>Natick</td>
<td>Mass.</td>
<td>Eli Lilly</td>
<td>2010 Q1-Q4</td>
<td>Speaking</td>
</tr>
<tr>
<td>Claus, Santa North Pole Hospital</td>
<td>Boston</td>
<td>Mass.</td>
<td>Johnson &amp; Johnson</td>
<td>2010 Q1-Q4</td>
<td>Travel</td>
</tr>
<tr>
<td>Claus, Santa North Pole Hospital</td>
<td>Boston</td>
<td>Mass.</td>
<td>Johnson &amp; Johnson</td>
<td>2010 Q1-Q4</td>
<td>Consulting</td>
</tr>
</tbody>
</table>
Example from ProPublica

<table>
<thead>
<tr>
<th>Name / Payee</th>
<th>City</th>
<th>State</th>
<th>Company</th>
<th>Period</th>
<th>Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frog, Kermit</td>
<td>WORCESTER</td>
<td>Mass.</td>
<td>GlaxoSmithKline</td>
<td>2009 Q2-Q4</td>
<td>Speaking</td>
<td>$6,000</td>
</tr>
<tr>
<td>Frog, Kermit</td>
<td>WORCESTER</td>
<td>Mass.</td>
<td>GlaxoSmithKline</td>
<td>2010 Q1-Q4</td>
<td>Speaking</td>
<td>$10,000</td>
</tr>
<tr>
<td>Frog, Kermit</td>
<td>WORCESTER</td>
<td>Mass.</td>
<td>GlaxoSmithKline</td>
<td>2011 Q1</td>
<td>Speaking</td>
<td>$10,000</td>
</tr>
</tbody>
</table>

Incomplete based on state and company disclosure databases.

PPSA & Data

Public Disclosures Aggregated By Kyruus in 2010, 2011
(Plus Projections Under PPSA)

With PPSA, Kyruus projects a 3-4x increase in publicly available data

*PPSA projections based on public disclosures from the Mass DPH and the top 20 companies under CIA.
Systems That Solely Focus on Internal Self-Reporting Lead to Significant Exposure and Discrepancies

<table>
<thead>
<tr>
<th>Study name</th>
<th>Source of self-reported disclosures</th>
<th>% of actual industry relationships not captured through self-reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEJM 2009</td>
<td>Society meeting – speaker, board member, and committee member disclosures</td>
<td>21-52%</td>
</tr>
<tr>
<td>J Vasc Surgery 2011</td>
<td>Other article disclosures from same author</td>
<td>28%</td>
</tr>
<tr>
<td>Kyruus client study A</td>
<td>Institution’s internally-collected disclosures</td>
<td>54%</td>
</tr>
<tr>
<td>Kyruus client study B</td>
<td>Institution’s publicly-rendered staff disclosures</td>
<td>42%</td>
</tr>
<tr>
<td>Kyruus client study C</td>
<td>Institution’s internally-collected disclosures</td>
<td>79%</td>
</tr>
</tbody>
</table>

Self-reported disclosures are historically unreliable, incomplete, and out-of-date

Monitoring and Verification, not disclosure

- **Almost 80%** of physicians have a financial relationship with the life sciences industry
- **2,000,000+** company-physician payments now disclosed on public websites
- Heightened regulatory scrutiny necessitates administrative monitoring and awareness
  - NIH research compliance
  - OIG medical necessity investigations
  - DOJ

The future will be payment monitoring & verification platforms to ensure data-driven conflict-of-interest management.
Physicians are concerned

A nation-wide survey of 100 physicians showed the following:

- **87%** of respondents would find pre-population of publicly available data in their disclosure system to be helpful.
- **87%** of respondents would be concerned or very concerned if they discover that publicly disclosed information is inaccurate.
- **78%** of respondents expect their compliance office to find and help manage their publicly-disclosed industry interactions.

The Value of Combined Approach

- To engage employees, physicians, and patients in improved transparency.
- To improve compliance.
- To minimize embarrassing industry relationship revelations.
- To reduce the amount of noise with which you need to deal.
SO, WHAT NEXT?

- Does this change your approach to your compliance work?
  - Conflict of interest
    - Financial
    - Clinical
  - Conflict of commitment
  - Stark and Anti-Kickback issues
  - Tax issue
- Does the increase of available data come with an increase in potential liability?

Considering you compliance processes

- Conflict of interest - Financial
  - Will you incorporate the availability of new data into your process?
    - Do you have an obligation to look?
    - Remember why Grassley pushed the PPSA
  - The new regulations obligating the institution to evaluate significant financial conflicts of interest.
    - We still rely on the researcher to self-report
  - What about timing issues
    - When is the data available?
    - What does it reflect – are you comparing apples and apples?
Considering you compliance processes

- Conflict of interest - Clinical
  - Do you have any obligation to look at your clinicians relationships?
  - Once you are aware of a relationship is there an obligation to inform?

- Conflict of commitment
  - Do you want time the these outside commitments require of the individual and not just the dollar figures?
    - Is this an integral part of the process anyway?

Assessing Stark and Anti-kickback issues

- Do you just consider relationships with pharma and device manufacturers?
- What disclosures are required by your conflict of interest process?
  - Does it go beyond those items mandated by federal and state laws?
- If you learn of a relationships that could have Stark and/or AKS implications what are your obligations?
- If you learn of a relationship that does not appear commercially reasonable what do you do?
What implications are there regarding your 990 form?

- As your organization evaluates what is reported on the 990 by your board and others should you be looking at the publically reported data?
- In reporting on your conflicts of interest policy will there be a shift in expectations that you incorporate looking at publically reported data?

Could the availability of public data increase your liability?

- Must you look?
- Should you look?
- What if you don’t look?
- How much should you look at?
- Will you need additional resources if you look?