Healthcare Professional Payment Disclosure

and

Potential Industry Impact

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Any opinions presented by the speaker are her own, and do not necessarily represent an official position of Pfizer Inc.
Transparency
Evolving External Landscape

Federal disclosure legislation (Senate and House)

State disclosure legislation

Medicare Payment Advisory Commission (MedPAC)

AMC Conflict of Interest Policies

Institute of Medicine (IOM) Report on Conflicts of Interest in Medicine

Corporate Integrity Agreements

Disclosing Payments to HCPs
A Number of Pharmaceutical Companies Have Played a Leadership Role in Promoting Transparency

Pfizer’s transparency efforts have included:

- Public reporting of U.S. political contributions (2002)
- Registering trials on clinicaltrials.gov (2002)
- Public posting of clinical trial results on clinicalstudyresults.org (2004)
- Reporting of FDA post-marketing commitments on Pfizer.com (2007)
- Reporting of non-clinical healthcare related grants & charitable contributions on Pfizer.com (2008)
- Launch of unbranded Medicine Safety website (2008)
- Announcement of HCP Payment Disclosure Initiative (2009)
Guiding Principles for Pfizer Voluntary HCP Payment Disclosure Initiative

• **Focus on patient needs**
  – Desire to better understand their information needs with regard to Pfizer’s interactions with healthcare professionals

• **Demonstrate respect for healthcare professional collaborations**
  – Explain the value of collaborations
  – Consider and address HCP concerns as appropriate

• **Do all we can to ensure that the public at large understands the work we do with HCPs.**
  – Develop a reader friendly disclosure system that provides context and explains the purpose of our collaborations
  – Provide accurate and timely information to all.
In February 2009, Pfizer Announced Its Voluntary HCP Payment Disclosure Initiative

Starting in March 2010, Pfizer will disclose payments to:

- All healthcare professionals who can prescribe medicines (includes physicians, NPs, PAs)
- Major institutions for ongoing clinical trials begun before July 1, 2009
- All principal investigators and other entities for Phase I-IV clinical trials sponsored by Pfizer beginning on or after July 1, 2009

Pfizer will disclose payments for:

- Consulting
- Promotional speaking
- Phase I-IV clinical trials
- Investigator-initiated research
- Meals and business-related travel
• **Reporting Thresholds & De Minimus Items**
  – In March 2010 posting, payments to individuals will be posted if recipient received ≥$500 in aggregate during 2009 from date tracking began
    • $500 Threshold eliminated per CIA starting with March 2011 posting
  – In March 2010 posting, the value of meals or business-related travel expenses under $25 will not be included in a recipient’s aggregate total toward $500.
    • $25 de minimus eliminated per CIA starting with March 2011 posting

• **Timing and Frequency**
  ▪ Annual disclosure on Pfizer.com starting on March 31, 2010 for payments made on or after July 1, 2009
    • Per CIA, quarterly posting of data starting in June 2011

• **Additional Disclosure Elements**
  ▪ Educational Items (e.g., textbook, anatomical models)
    ▪ Disclosure required per CIA
Impact of HCP Payment Disclosure

Operational Considerations

- HCP spend is required to be captured across various systems and divisions
  - Not a simple scale up of state law reporting processes
  - Need for more automated data collection and validation processes
- Appropriate data collection processes and habits need to be established in every department that is involved in any way with HCP related spend
  - Need for rollout of policies and training across the organization
- Data collection challenges with respect to CSOs and vendors
  - Contractual obligations and business rules
  - Data systems may not feed automatically
- Need for Data Accuracy
  - Robust quality control and audit processes
  - Consider need for feedback loop (eg, call center, mailbox) to enable physicians to followup with company on questions regarding posted data

One Approach

Data Inputs, incl:
- Expense Reports (meals)
- Contracts
- Accounts Payable Systems
- Clinical Trials
- Speaker Programs
- Consulting

Verification Process
ensure individual payments Are associated with the Right person

QC Process
Process to review and ensure data accuracy

Public Posting of Data

Feedback Loop
Impact of HCP Payment Disclosure

Potential Business Impact

Based on Preliminary Research/Feedback:

**Speakers and Consultants**
- Most physicians that were surveyed or that provided feedback support or are neutral to publicly posting compensation for services.
- A small percentage of physicians have expressed concern indicated they will not collaborate with industry because of this issue.
- The primary concern raised by physicians is about how their patients would view them in light of their collaborations with industry.
- Many discussed the need to educate the public about the value of these collaborations.

**Clinical Trial Investigators**
- Most investigators surveyed did not anticipate disclosure impacting willingness to be an investigator.
- Concern by investigators that posted clinical trial payments will be misconstrued as remuneration to the investigator.
Impact of HCP Payment Disclosure
Some Feedback from Other Stakeholders

• **Consumers**
  – Preliminary feedback suggests there is not a clear understanding about transparency and the nature of paid collaborations with healthcare professionals

• **Medical Societies**
  – Several stakeholders have expressed an interest in helping their members prepare to address patient concerns regarding disclosure

• **Academic Medical Centers**
  – Requests to review payments to ensure AMC policies are being complied with
Impact of HCP Payment Disclosure

Reputational Impact

• Increasing Public Disclosure of Business Practices
  – to address public concerns
  – help manage perceived conflicts of interest
  – meet external requirements

• Will transparency increase public trust in the industry?

• Will transparency bring further criticism of industry practices?