



*Advising the Congress on Medicare issues*

# Public reporting of physicians' financial relationships: Policy options

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September 4, 2008

# Outline

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- Chapter in MedPAC's June 2008 report; interest in a public reporting system
- Physicians' financial relationships with drug and device manufacturers
  - Background
  - Proposed framework for public reporting system
  - Highlight key questions
- Physicians' relationships with hospitals and ambulatory surgical centers (ASCs)
- Future meeting: Draft recommendations

## Background: Financial relationships between physicians and drug/device manufacturers are pervasive

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- Most physicians have interactions with drug manufacturers (Campbell et al. 2007)
- Drug companies spent \$7 billion on physician detailing and provided free samples worth \$18 billion in 2005 (Donohue et al. 2007)
- “Medical schools...have become increasingly dependent on industry support of their core education missions” (AAMC 2008)
- Device companies also have financial ties to physicians related to product development, education, training, and research

# Benefits and risks of industry-physician relationships

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- Relationships can lead to technological advances, increased use of beneficial products
- But may also undermine physicians' independence, objectivity
- Industry interactions associated with
  - Rapid prescribing of newer, more expensive drugs
  - Requests to add drugs to hospital formulary (Wazana 2000)
- Clinical research funded by manufacturers not always objective and publicly available (Bekelman et al. 2003)

# Efforts by private sector and government to regulate relationships

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- Development of voluntary guidelines by manufacturer and physician groups
- OIG issued guidance to help companies comply with anti-kickback law
- No mechanism to track compliance with guidelines
- Evidence that some inappropriate practices persist
- Several academic medical centers and medical groups have adopted strict policies to limit interactions with industry

# State reporting laws

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- 5 states and DC require manufacturers to publicly report payments to physicians
- Only Massachusetts' law covers device manufacturers
- Data often incomplete and not easily accessible
- Vague definitions of payment categories

# Advantages of national database on physician-industry relationships

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- Could discourage inappropriate arrangements
- Press/researchers could shed light on potential conflicts of interest
- Payers and plans could examine physicians' practice patterns

# Concerns about national database on physician-industry relationships

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- Compliance costs for manufacturers
- Administrative costs for government
- Might discourage beneficial arrangements
- Would not eliminate conflicts of interest

# Proposed framework for reporting system based on 3 key design questions

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- How comprehensive should system be?
- What size and types of relationships should be reported?
- Should federal law preempt state laws?

# Proposed framework: How comprehensive system should be

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- Which types of manufacturers should be included?
  - Drug, device, and supply companies; large and small
- Should payments to recipients other than physicians be included?
  - Include academic medical centers, continuing medical education organizations, patient advocacy and physician organizations

## Proposed framework: How comprehensive system should be (cont.)

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Should companies be allowed to withhold information they deem proprietary?

- Tradeoff between protecting trade secrets and public transparency
- Perhaps allow delayed reporting of payments related to development of new products; delay could be tied to when...
  - Clinical trial is registered on NIH website, or
  - FDA approves new product, but no later than a set number of years after payment made

# Proposed framework: Size and types of payments to report

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- \$25 threshold for payments that must be reported
- Types of payments to include
  - Gifts, meals, entertainment, honoraria, consulting, education, speakers' fees, research, investment interests, product royalties

# Proposed framework: Size and types of payments to report (cont.)

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## Should free samples be reported?

- Would increase compliance costs for industry
- But would provide more complete picture of industry relationships with physicians
  - 78% of physicians received drug samples in last year (Campbell et al. 2007)
  - Drug companies provided free samples worth \$18 billion in 2005 (Donohue et al. 2007)

# Should federal reporting law preempt state laws?

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- Preemption would reduce compliance costs for manufacturers, but would limit state autonomy
- Perhaps allow states to collect information not collected under federal law
  - But companies might have to comply with multiple laws, increasing their costs

# How to make data readily accessible to the public?

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- Create database on Internet
- Clearly define payment categories
- Allow users to search for payments by type, amount, physician, and manufacturer

# Implementation issues

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- Which agency should administer system?
  - Allow Secretary to choose (options include FDA, CMS, OIG)
- Administrative costs are unclear
  - According to Minnesota, cost of collecting and posting information is minimal (but no searchable electronic database)
  - No data on enforcement costs
  - May want to ask Congress to provide sufficient resources to Secretary

## Growth of physician investment in hospitals and ASCs may signal need for more information

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- Physician-owned specialty hospitals more than tripled, 2002-2008
- Ambulatory surgical centers grew by 60%, 2000-2007
- Increase in joint ventures and other financial arrangements between hospitals and physicians
  - Concern that some arrangements might increase volume without improving quality and coordination
- Difficult for payers and researchers to obtain information on financial relationships
  - Important to understand how financial ties affect referrals, quality, and costs

# Current rules on hospital disclosure of financial relationships with physicians

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- Hospitals enrolling in Medicare must report individuals who own 5% or more of hospital, but data not publicly available
- CMS requires hospitals to inform Medicare patients if physician owned, but information not available to CMS or public
- CMS will collect detailed data on relationships from sample of hospitals (Disclosure of Financial Relationships Report)

# Options for public reporting of hospitals' financial relationships with physicians

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- Require all hospitals to report all physician owners to CMS, which would post on website
  - CMS already collects data on physicians who own 5% or more
- Require hospitals to publicly report additional financial relationships (e.g., joint ventures, leases)
  - Need to balance transparency with administrative burden on hospitals
  - May be prudent to wait for review of information collected on DFRR

## Current rules on ASC disclosure of physician ownership

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- ASCs enrolling in Medicare must report individuals who own 5% or more of ASC, but data not publicly available
- CMS proposed requiring all ASCs to disclose physician ownership to Medicare patients, but data would not be available to CMS or public
- Physician-owned ASCs that comply with anti-kickback safe harbors must disclose ownership to patients

# Option for public reporting of physician ownership by ASCs

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Require all ASCs to report all physician owners to CMS, which would post on website

- CMS already collects data on physicians who own 5% or more

# Seeking guidance to shape draft recommendations

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- Reactions to proposed framework for public reporting system for drug/device manufacturers
- Feedback on options for public reporting by hospitals and ASCs