



*Advising the Congress on Medicare issues*

# Public reporting of physicians' financial relationships: Draft recommendations

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# Background

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- Financial relationships between physicians and drug/device manufacturers are pervasive
- Industry-physician ties have benefits and risks
- Efforts by private sector and government to regulate relationships
- 5 states and DC require manufacturers to publicly report payments to physicians

# Advantages of national database on physician-industry relationships

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- Could discourage inappropriate financial arrangements
- Media/researchers could shed light on relationships
- Payers and plans could examine whether industry ties affect physicians' practice patterns
- Academic medical centers could verify financial interests of researchers
- Hospitals could check whether physicians involved in purchasing decisions have financial ties

# Costs and limitations of 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
- Information may be of limited use to patients

# Reporting system would apply to broad set of manufacturers and recipients

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- Manufacturers of drugs, biologicals, devices, and supplies
  - Include small and large companies
  - Include subsidiaries
- Recipients of payments
  - Physicians and other prescribers
  - Hospitals and medical schools
  - Professional and patient advocacy organizations
  - Organizations that sponsor CME

# Threshold for payments that should be reported

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- Manufacturers should report payments if total annual value of payments to a recipient exceeds \$100
- Adjust threshold annually based on inflation

# Types of relationships to report

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- Gifts, food, entertainment, honoraria, research, funding for education and conferences, consulting fees, investment interests, product royalties
- Exclude discounts, rebates, free samples for patient use
- Companies should report
  - Value, type, date of each payment
  - Name, specialty, Medicare billing number (if applicable), and address of each recipient

# Guidelines for reporting payments related to new product development

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- Tradeoff between protecting sensitive information and public transparency
- May delay reporting of payments related to clinical trials until trial is registered on NIH website
- May delay reporting of other payments related to development of new product until FDA approval, but no later than 2 years after payment made

# Federal reporting law should preempt equally or less stringent state laws

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- Strike balance between state autonomy and advantages of national system
- Preempt state laws that collect data on same types of financial relationships and recipients as federal law

# Other design issues

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- Authority to assess civil penalties on manufacturers for non-compliance
- Require manufacturers to investigate and correct reported errors in timely fashion
- Information should be reported annually
- Allow companies to report clarifying information about payments

# Implementation issues

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

# Physician investment in hospitals and ASCs is growing

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- Physician-owned specialty hospitals more than tripled, 2002-2008
- Ambulatory surgical centers grew by 60%, 2000-2007
- Difficult for payers and researchers to obtain information on ownership and financial relationships
  - Important to understand how financial ties affect referrals, quality, and costs

# Current rules on hospital and ASC disclosure of financial relationships with physicians

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- Hospitals and ASCs—that are structured as corporations—must report individuals owning a 5% or larger interest to CMS (direct and indirect)
- Hospitals and ASCs structured as partnerships must report all partners to CMS
- CMS requires hospital patients be informed of physician ownership
- However, none of this information is available to researchers and the general public

# Disclosure of other physician-hospital financial relationships

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- Increase in financial arrangements between hospitals and physicians
  - Concern that some arrangements might increase volume without improving quality and coordination
- Could require hospitals to publicly report additional financial relationships (e.g., employment, leases)
  - Need to balance transparency with administrative burden on hospitals
  - May be prudent to wait for review of information collected on the Disclosure of Financial Relationships Report (DFRR)

# Disclosure of Financial Relationships Report (DFRR)

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- Current emphasis of DFRR is on enforcement of the self referral statute
- CMS has not proposed to publicly report financial relationships
- A report on the prevalence of various arrangements (based on the DFRR) could inform future decisions on what types of relationships hospitals should publicly report