Public reporting of physicians' financial relationships with drug and device manufacturers, hospitals, and ASCs

Ariel Winter, Jeff Stensland, Hannah Neprash

March 5, 2008

MEDPAC

Why should we be concerned?

- Medicare spent $44 billion on Part D (2006)
- Medicare spent $10 billion on Part B drugs (2005)
- Medicare spends significant amount on implantable devices (e.g., artificial knees and hips, stents)
- Growth of physician investment in ASCs and specialty hospitals

Financial relationships between physicians and manufacturers are pervasive

- Most physicians have interactions with drug manufacturers (Campbell et al., *NEJM*, 4/26/07)
- Device manufacturers have financial ties to physicians related to new product development, education, training, and research
- 4 orthopedic implant companies paid physician consultants over $800 million, 2002-2006 (OIG, 2008)

Benefits and risks of industry-physician relationships

- 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
  - Lower prescribing of generics
  - Requests to add drugs to hospital formulary (Wazana, *JAMA*, 1/19/00)

Efforts by private sector and government to regulate relationships

- Prosecutions of manufacturers under federal fraud and abuse laws led to large settlements
- Development of voluntary guidelines by manufacturer and physician groups
  - PhRMA and AdvaMed: permit modest, occasional gifts for patient benefit; bona fide consulting arrangements
- OIG issued guidance to help companies comply with anti-kickback law (payments can not be used to induce the use of a product)

Are the guidelines adequate?

- Some evidence that companies focusing more on compliance
- But no mechanism to measure/enforce compliance with voluntary guidelines
- Evidence that some inappropriate practices may persist
- Critics claim that guidelines are too vague, not stringent enough

Several organizations and states are adopting stricter policies

- Some academic medical centers (e.g., Stanford, UMass) prohibit physicians from accepting gifts or samples
- Permanente Medical Group forbids physicians from accepting payments or travel expenses from industry for speeches or presentations
- Minnesota bans companies from giving gifts and meals > $50
- 4 states and DC require drug manufacturers to report payments to physicians

Type of payments included in reporting programs

	MN	DC	VT	ME	WV
Year of legislation	1993	2001	2003	2003	2004
Disclose payments greater than	$100	$25	$25	$25	$100
Educational programs / materials	Y	Y	"any gift, fee, payment, subsidy or other economic benefit provided in connection with…marketing activities"	Y	"gifts, grants, or payments of any kind" which are "provided directly or indirectly"
Food/entertainment / payments	N/A*	Y		Y	
Honoraria / consulting fees	Y	Y		Y	
Clinical trials / research	Y	N	N	N	N
Free samples for patients	N	N	N	N	N
Medical conferences	Y	N	N	N	N
Continuing Medical Education	Y	Y	N	Y	Y
Drug rebates / discounts	N/A*	Y	N	Y	N

Y = Yes N = No * These payments are banned under Minnesota law if in excess of $50.
Source: Lurie, Peter. 2007. Oral testimony before the Select Committee on Aging, U.S. Senate. 110th Cong., 1st sess. June 27.

MEDPAC

Problems with data completeness and availability

- VT, ME, WV and DC compile an annual report of payments in aggregate, but don't disclose payments by physician or manufacturer
- Only MN makes detailed information available online, but not searchable
- Vague definitions of payment type and purpose (Ross et al., *JAMA*, 3/21/07)
- Vermont allows companies to withhold payments designated as "trade secrets"

Should there be a federal law requiring reporting of financial relationships?

- Current state laws are insufficient
- National data could be used by
  - Payers and health plans
  - Hospitals
  - General public and researchers

Payers/plans could use data to examine physician practice patterns

- Do financial relationships influence use of drugs and devices, overall resource use?
  - Example from Minnesota data: psychiatrists who received more money from manufacturers of atypical antipsychotics prescribed them to children more frequently (*New York Times*, 5/10/07)
- Plans could use information to construct provider networks

Hospitals could use data to….

Check if physicians have potential conflicts of interest when they

- Serve on formulary committees
- Request that drugs be added to formulary
- Request that hospitals purchase specific implantable devices

General public and researchers could use data to…

- Track whether companies comply with industry guidelines
- Evaluate whether authors of clinical guidelines and journal articles have potential conflicts of interest
  - Most physicians who wrote guidelines had relationships with drug companies, but very few were disclosed (Choudhry, *JAMA,* 2/6/02*)*

MEDPAC

Concerns about public reporting

- Will data be useful to patients?
  - Difficult for patients to judge if physician's recommendation is appropriate
- Reporting will not eliminate conflicts of interest
- Burden on manufacturers (to report information) and government (to administer law)
  - But perhaps easier to comply with uniform reporting rules than different state laws

Design and implementation issues

- Include drug and device manufacturers?
- Which types of relationships should be reported?
  - Possibilities: investments in company, royalties, consulting, honoraria, conferences, education, research, gifts, meals, samples
- Where should the dollar threshold be set for reporting?
- Should each payment be itemized?
- Should companies be allowed to withhold information as trade secrets?

Design and implementation issues (cont.)

- How to make information easy to use?
  - E.g., online searchable database, standardized payment categories
- Which agency should collect data and maintain database?

Growth of physician investment in ASCs & hospitals may signal need for improved disclosure

- Ambulatory surgical centers (ASCs) grew by over 60%, 1999-2006
  - Most ASCs have physician ownership (MGMA)
- Physician-owned specialty hospitals more than doubled, 2002-2006
- Joint ventures and other financial arrangements are expanding but are difficult to track given lack of ownership information

Current federal disclosure requirements are incomplete

- Most information on financial relationships not available to payers, general public, and researchers
- Hospitals must disclose physician ownership to patients
- CMS proposes same requirement for ASCs
- Hospitals must disclose owners of 5% interests to CMS
- CMS proposes requiring sample of 500 hospitals to complete detailed survey of physician-hospital relationships (some hospitals declined earlier voluntary survey)

Public reporting could be more streamlined, searchable, and consistent

- Option: searchable data base where hospitals and ASCs annually disclose
  - Physician ownership interests and percent of interest
  - Lease, joint venture, and certain other financial relationships between physicians and hospital
- Less detailed disclosure than CMS's proposed survey

Questions for Commissioners

- Should manufacturers, hospitals, and ASCs be required to publicly report their financial relationships with physicians?
- Are there next steps we should pursue?