CMS Finally Issues Proposed Sunshine Act Regulations

January 3, 2012

Judy Waltz, Partner — Foley & Lardner LLP
“Sunshine Act” Provisions  
42 U.S.C. §1320a-7h  
Soc. Sec. Act §1128G  
42 C.F.R. Parts 402 and 403

Proposed Rule  
Road Map

- Context for the push for transparency.
- Statutory Overview.
- Key Provisions of the Proposed Rule.
Physician Participation in Industry Arrangements (2007)

- 94% of physicians self-report some type of relationship with industry;
- 83% report receiving food and beverages in the workplace;
- 78% report being given drug samples;
- 35% report reimbursement for meeting costs or CME; and
- 28% report payments for consulting, speaking, or enrolling patients in trials.

Consumers say Big Pharma Influence on Docs is Concerning

- 69 percent of consumers surveyed think drug makers have too much influence on doctors’ decisions about which drug to prescribe.

- Half of those polled feel doctors are too eager to prescribe a drug rather than consider alternate methods of managing a condition.

- 47 percent said they think gifts from pharma companies influence doctors to prescribe certain drugs, with 41 percent saying they think doctors tend to prescribe newer, more expensive drugs.

Consumer Reports Health Blog (8/14/2010)
Orthopedic DPAs (2007)

- First cases to require public (internet) disclosures of payments to HCPs.
- “Payment” shall include any and all compensation or remuneration paid to or for the benefit of Consultants, including but not limited to payments and reimbursements for personal or professional services, any type of securities, registered or unregistered, meals, entertainment, travel, gifts, grants, honoraria, charitable contributions, donations, sponsorships, research grants, clinical studies, professional meetings, product training, medical education, research funding, product development services, in-kind services (e.g., use of aircraft), advertising, promotion, and marketing expenses or support, and royalties or other payments for transfer of documented intellectual property. [Zimmer DPA]
Zimmer DPA (2007)

- Within thirty (30) calendar days of the Effective Date of this DPA, the Company shall prominently feature on its web site the name, city, and state of residence for each of the Company’s Consultants who were retained at any time in 2007, who provided Consulting Services to the Company at any time in 2007, or who received any Payments from the Company in 2007.

- The Company shall also disclose the Payments made to each Consultant to date in 2007 within $25,000 increments, and, within sixty (60) calendar days of the Effective Date, all other Payments made in other than dollar form.

- Within ten (10) calendar days after a new Consulting Agreement or renewal is executed, the Company shall post the name of the Consultant on its web site. If the Company has or does enter into a Consulting Agreement with an entity rather than an individual, the Company shall post both the name of the entity and the individual providing Services to the Company under the Consulting Agreement. Payment information shall be updated quarterly during the term of this DPA to reflect the total Payments made to each Consultant within $25,000 increments, and all other Payments made in other than dollar form. The Company must also disclose this information to the Consultant’s affiliated hospitals.
Doctors Given Millions by Device Makers Fail to Disclose Pay in Research

“Fewer than half of the physicians who received $1 million or more in consulting fees from medical device companies including Johnson & Johnson, Stryker Corp. and Biomet Inc. in 2007 disclosed the financial ties in subsequent articles they wrote about the industry, a study shows.”

Source: Bloomberg, Sep 13, 2010, Article by Michelle Fay Cortez
Corporate Integrity Agreements

“Sunshine Provisions.”

- Why the OIG’s concern if (pre-PPACA) no federal law which requires reporting of HCP gifts or imposes a ban on accepting gifts?

- General goal of transparency in healthcare operations.

- Concern about skewed decision-making influenced by gifts.

- Anti-kickback statute may be implicated by payments to HCPs if referrals or purchases may result from those payments.
  - Stark arrangements.
Federal Statute
Statutory Overview

- Sunshine Act provisions initially introduced in 2007. (Sens. Grassley and Kohl)
- PPACA [2010 Health Care Reform] Section 6002, 42 U.S.C. § 1320a-7h
- No “Gift Ban,” just reporting requirements
Proposed Rule:

- “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests”
Proposed Rule - Summary

“Applicable manufacturers” of drugs, devices, biologicals or medical supplies covered by Medicare, Medicaid, or Children’s Health Insurance Program will be required to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals (“covered recipients”).
Proposed Rule – Summary (cont.)

- Applicable manufacturers and group purchasing organizations (GPOs) will be required to report annually certain physician ownership or investment interests.
- Secretary is required to publish applicable manufacturers’ and applicable GPOs’ submitted payment and ownership on a public website.
Proposed Rule – Key Dates

- Comments due: February 17, 2012.
- Statutory due date for first reports: March 31, 2013 (information to be collected after January 1, 2012)
- Collection commencement delayed until after Final Rule is issued, plus probable preparation period of 90 days.
- CMS indicates partial year data likely to be required, submitted for March 31, 2003 date (comments welcome as to feasibility).
“Applicable Manufacturer” defined.

- Proposed [Statute: Section 1128G(e)(2) and (9)].
- regulation (§ 403.902):
  - (1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or
  - (2) Under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.
“Applicable Manufacturer” – Key Points

- Definition met if products sold or distributed in U.S., regardless of where product is produced or entity is located.
- Definition met if at least one covered product is sold or distributed in U.S.
  - All payments or transfers of value must be reported regardless of whether the payment is associated with a covered product.
- Definition met for entities that hold FDA approval, licensure or clearance for a product, even if they contract out the manufacturing to another entity.
“Applicable Manufacturer” – “Common Ownership”

- Proposed definition: when the same individual, individuals, entity, or entities, directly or indirectly own any portion of two or more entities. Includes parent companies, subsidiaries, and brother/sister corporations.

- Alternate interpretation under consideration – limit to 5 percent or more of total ownership in two or more entities. Comments invited.
“Common Ownership” – How Many Reports?

- Two or more entities under common ownership, both meet definition of applicable manufacturer under para. (1): then both must report.
- Two or more entities under common ownership, only one meets definition of applicable manufacturer under para. (1), and other company required to report under para. (2): then choose whether to report as one or two.
“Applicable Manufacturer” – Third Party Payments

- Manufacturers must report payments or transfers of value if the applicable manufacturer is aware of the identity of the covered recipient.
“Covered Drug, Device, Biological or Medical Supply”

- **Definition**
  - [Statute: 1128G(e)(5)]
  - Proposed Regulation: 42 C.F.R. § 402.902
  - *Any* drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.
“Covered Drug, Device, Biological or Medical Supply” - Key Points

- Definition will include products paid for under a composite payment system (e.g., hospital DRGs, ESRD-PPS), as well as those reimbursed separately.
- Drugs and biologicals limited to those for which a prescription is required; OTC excluded.
- Devices and medical supplies limited to those which by law require premarket approval by or notification to FDA; manufacturers limited to these products would not be required to report at all.
“Covered Recipients”

- Defined: 42 C.F.R. § 403.902
  - Statute: Sec. 1128G(e)(6): (1) Physician, other than a physician who is an employee of an applicable manufacturer; or (2) a teaching hospital.
  - Physician defined: 1128G(e)(11) – same as S/S Act 1861(r).
  - Employee defined: 1128G(e)(7) – same as common law rules as applied by IRS.
  - Teaching hospital: not defined in statute.
    - Proposed Rule: any institution that received payments under IME or GME.
“Covered Recipients” - Identification

- Physicians – requires NPIs (Proposed Rule notes information is publicly available at National Plan & Provider Enumeration System (NPPES)).
  - Considering some alternative unique identifier for those who do not have NPIs – comments requested as to what?

- Teaching Hospitals – CMS to publish a list of hospital covered recipients (those who get IME or GME) on CMS website once per year.
“Payments or Other Transfers of Value”

- Statute: 1128G(e)(10)(A) = “transfer of anything of value.”
- Proposed rule: 42 C.F.R. § 403.902
  - Includes payments regardless of whether the covered recipient specifically requested the payment.
  - Payments through a physician group or practice to be reported individually under the name of the physician.
  - Includes payments requested by a covered recipient for another individual or entity – reported under the name of the requester.
Payment and Other Transfer of Value – Report Content

- Name.
- Business Address (for physicians, primary practice location).
- Specialty and NPI.
- Date of Payment (discretion in determining).
- Associated Covered Drug, Device, Biological or Medical Supply (if available).
- Form of Payment, e.g., cash or cash equivalent, in-kind items, stock, any other as determined by Sec’y.
- Nature of Payment, e.g., consulting fees, honoraria.
Transparency Reports - Payments or Transfers of Value *Included by Statute*

- Consulting fees
- Other compensation for services
- Honoraria
- Gifts
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable Contributions

- Royalty or license payments
- Current or prospective ownership or investment interests
- Compensation for serving as faculty or speaker for CME
- Grants
- Any other payment or transfer of value as defined by HHS
Included Transfers – Charitable Contributions

- Charitable contributions to, at the request of, or on behalf of covered recipients by an applicable manufacturer must be reported.

- “Charitable contribution” is any payment or transfer of value made to an organization with tax-exempt status and not more specifically described by one of the other nature or payment categories.
Included Transfers – Food and Beverage

- Group meals in group settings (e.g., buffet in physician office) – report cost per covered recipient (even if the covered recipient does not actually partake). Solo practice would be one covered participant, so entire cost reported for that doctor; group practice would divide the cost between number of doctors.

- Buffet meals, snacks or coffee at booths at conferences or similar events would not be reported as it would be difficult for applicable manufacturers to definitively establish the identities of individuals who were partaking.
Included Transfers - Research

- Limit to bona fide research, including clinical investigations that are subject to both a written agreement or contract, as well as a research protocol (note import for delayed reporting).

- CMS notes the difficulties because payments may be spread across numerous activities and parties; also payments often not provided directly to a covered recipient but rather to a clinic, hospital or institution.
Proposal is:

- To separate the classification of research payments by whether the payment went indirectly or directly to the covered recipient, with manufacturer to identify as follows:
  - Indirect – to clinic, hospital (other than teaching hospital) or institution.
  - Direct – to physician covered recipient or teaching hospital covered recipient.

- Report under names and NPIs of physician-covered recipients serving as principal investigators (both direct and indirect).
  - Indirect payments should also indicate name of entity or individual that actually received the payment.
Payments to Teaching Hospitals – both hospital and physician should be reported as recipients – hospital as direct, physician as indirect.

Total research payment is reportable for physician even though more than physician services involved – too hard for applicable manufacturer to allocate expenditures; however, on public website, payment would be reported separately and not aggregated into physician totals.
Included Transfers – Faculty and Speakers

- Proposal is to include all instances in which applicable manufacturers pay physicians to serve as speakers, not just CME.
Included Transfers – “Other”

- Any payments or transfers of value that are not specifically excluded, and do not fit into another category should be reported as “other.”
Transparency Reports - Payments or Transfers of Value *Excluded by Statute*

- Items with a value of less than $10, unless the aggregate amount exceeds $100 in a calendar year.
- Product samples intended for patient use.
- Educational materials that directly benefit patients.
- Loans of covered device for a trial period not to exceed 90 days.
- Items or services provided under a contractual warranty.
- Discounts and rebates.
- Transfers to a covered recipient not acting in a professional capacity as such.
- In kind items used for the provision of charity care.
- Dividends or other profit distributions from or ownership or investment interest in, publicly traded securities and mutual funds.
Transfers of Value – Exclusions – Key Points

- Payments less than $10 – excluded except when total annual value > $100.
  - Amounts to be increased annually in accordance with CPI for all urban consumers.

- Educational Materials – must be materials and not services or items; CMS considering whether to include materials used by covered recipients.

- Discounts and Rebates – reminder as to obligation to report.
In-kind Items for Charity Care

- In-kind items for the Provision of Charity Care – items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive payment.
  - Excluded from reporting.
  - Does not include situation where non-charity care is involved (items provided to ALL patients).
Exclusions – Indirect Payments Through Third Party

- Applicable manufacturer must be unaware of the identity of the covered recipient – standard is actual knowledge, or acts in deliberate ignorance or reckless disregard, of the identity of the covered recipient.
Reports on Physician Ownership and Investment Interests

- Statute: Section 1128G(a)(2) requires applicable manufacturers, as well as applicable GPOs, to report certain information concerning ownership and investment interests held by physicians or their immediate family members in such applicable manufacturers and applicable GPOs, and payments or other transfers of value to such physician owners and investors.
Reports on Physician Ownership and Investment Interests

- Applicable GPOs – defined in regulation as:
  
  An entity that (1) operates in the United States, or in a territory, possession or commonwealth of the United States, and (2) purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

- CMS says that this definition will include not only traditional GPOs, but also entities that purchase products for resale or distribution to groups of individuals or entities, specifically including POD (physician owned distributors).
Reports on Physician Ownership and Investment Interests (cont.)

- Definition of covered products limited to drugs and biologicals that require a prescription to be dispensed.

- Definition of covered products limited to devices (including medical supplies) that require premarket approval by or notification to FDA (but CMS notes this may be overly limiting).
Reports on Physician Ownership and Investment Interests (cont.)

- Statute uses the term “physician” as defined in section 1861(r) of the Act, ergo, reports must include any physician, regardless of whether the physician is an employee of the applicable manufacturer or GPO.

- “Immediate family member” tracks definition of section 1877(a) of Act, 42 C.F.R. § 411.351.

- “Ownership interest” – direct or indirect, debt, equity or other means – not a publicly traded security or mutual fund, retirement plan, and some other exceptions.
Reports on Physician Ownership and Investment Interests (cont.)

- If report required from applicable manufacturer under section 1128G(a)(1) and (a)(2), report only under (a)(1).
- CMS recommends separate file for each to avoid duplicative postings; note for reports under (a)(1) when there is also an ownership or investment interest under (a)(2).
- Applicable GPOs – no report required under (a)(1); but if payments or transfers of value to their physician owners and investors, use the data elements identified there.
Publication Delays - Statute

- Delayed publication (not report) for payments pursuant to:
  - Product research or development agreement.
  - Clinical investigation [experiment involving 1 or more human subjects, or materials derived from human subjects, in which drug or device is administered, dispensed, or used].

- Delayed for lesser of:
  1. FDA approval/clearance or;
  2. 4 years after the date of payment/transfer of value.
Publication Delays – Proposed Rule

- Relationships must be for bona fide research or investigation activities, which if made public would damage competitive and/or proprietary interests.
  - Written statement or contract plus written research protocol; clinical investigation must be memorialized in a written research protocol.
- Manufacturers must indicate on their reports if publication delay is applicable; must be reported each year with indication that delay should continue.
- Following FDA approval, licensure or clearance, next annual report must indicate delay is no longer appropriate.
- “Medical technology” – any drug, device, biological or medical supply – CMS is seeking input.
- Available for new products plus new uses.
Reporting Mechanics – Data In

- CMS hoping for corrections in data prior to submission to CMS – applicable manufacturers share data with covered recipients prior to submission?

- Suggestion of possible pre-registration prior to submission – first opportunity in January 2013.

- Alternative: require all applicable manufacturers and GPOs to register, require certification if “nothing to report” from top management.

- Sample report formats – addendums to the display version of the Federal Register.
Reporting Mechanics – Data Review

- Statute requires 45 Day review period for applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors, prior to data being made available to public.

- After due date passes, data will be aggregated by individual covered recipient and physician owner or investor, across applicable manufacturers and applicable GPOs.

- Provisions for dispute resolution.
Reporting Mechanics – Public Availability

- Statute requires publicly available website.
- Will include specific data elements.
- Will include any enforcement activities taken under Section 1128G for the previous year.
- Delayed reports finally published.
State Preemption (Sec. 1128G(d)(3))

- Preemption of State Laws:
  - If they require manufacturers to report the same “type of information.”
  - Not for other types of disclosures or other entities.
  - Doesn’t address “gift bans.”

- Proposed Rule: Same information could be collected by Federal, State or local governmental agency for public health surveillance, investigation, or other public health purpose or health oversight.
Penalties (Section 1128G(b))

- $1,000 to $10,000 for each failure to submit required information in a timely manner, not to exceed $150,000 per annual submission.
- $10,000 to $100,000 for each knowing failure, not to exceed $1,000,000.
- Penalties are for each payment or other transfer of value.
- “Knowingly” = False Claims Act standard.
Penalties (Section 1128G(b))

- Procedures in Part 402 Subpart A apply for imposition and appeal.
- Factors:
  - length of time failed to report, including time knew about issue.
  - Amount of payment or value of interest.
  - Level of culpability.
  - Nature and amount of information reported in error.
  - Degree of Diligence exercised.
- Audits contemplated.
This Addendum will not appear in the Code of Federal Regulations.

**Addendum: Sample Reporting Template**

**Table A: Payment or Other Transfer of Value Template**

**Notes:**

This is a sample template for illustrative purposes, and is subject to changes.

Please submit this template as a Comma Separated Value (CSV) file.

Recipient = Covered Recipient or Physician Owner or Investor

Form of payment must be 1) cash or cash equivalent, 2) in-kind items or services, 3) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

Nature of payment must be 1) Consulting fee, 2) Compensation for services other than consulting, 3) Honoraria, 4) Gift, 5) Entertainment, 6) Food and beverage, 7) Travel and lodging, 8) Education, 9) Direct Research, 10) Indirect Research, 11) Charitable contribution, 12) Royalty or license, 13) Current or prospective ownership of investment interests, 14) Direct compensation for serving as a faculty or as a speaker for a medical education program, 15) Grant, or 16) Other.

<table>
<thead>
<tr>
<th>Reporting Entity</th>
<th>Recipient Name</th>
<th>Recipient Business street address</th>
<th>Recipient Specialty (physician only)</th>
<th>Recipient National Provider Identifier (NPI) (physician only)</th>
<th>Amount of Payment (US dollars)</th>
<th>Date of Payment</th>
<th>Form of Payment</th>
<th>Nature of Payment</th>
<th>Name of Associated Drug, Device, Biological, or Medical Supply (if necessary)</th>
<th>Entity Paid Name</th>
<th>Physician Owner or Investor (y/n)</th>
<th>Delayed Publication (y/n)</th>
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TABLE B: SAMPLE PHYSICIAN OWNERSHIP OR INVESTMENT INTEREST TEMPLATE

Notes:

This is a sample template for illustrative purposes, and is subject to changes.

Please submit this template as a Comma Separated Value (CSV) file.

Owner = Physician Owner or Investor.

All payments or other transfers of value provided to physician owners or investors must be reported on the Payment & Transfer of Value tab and designated as that to a physician owner or investor.

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<tr>
<th>Reporting Entity</th>
<th>Recipient Name</th>
<th>Recipient Business street address</th>
<th>Recipient Specialty *physician only</th>
<th>Recipient National Provider Identifier (NPI) *physician only</th>
<th>Interest Held by Immediate Family Member (y/n)</th>
<th>Dollar Amount Invested</th>
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Questions?

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