**THE PHYSICIAN PAYMENTS SUNSHINE LAW**

A teaching hospital guide to industry transparency reporting requirements.

### What is the Physician Payments Sunshine Act?

Signed into law in 2010 as part of the Affordable Care Act, the Physician Payments Sunshine Act (the “Sunshine Law”) requires manufacturers, including certain distributors, of medical devices, drugs, biologicals, and medical supplies to track and report certain payments made to, or transfers of value provided to physicians and teaching hospitals.

### Why was the Sunshine Law Enacted?

The main purpose of the Sunshine Law is to provide patients with enhanced transparency into the relationships their health care providers have with life science manufacturers, including medical technology companies. It’s important to note that the Sunshine Law does not restrict industry-physician collaboration or interactions, or prohibit payments or transfers of value. Rather, it requires tracking and reporting of payments and transfers of value that result from these interactions.

### Where can I find more information?

The Official CMS Website for the Sunshine Law, also referred to as the National Physician Payment Transparency Program: OPEN PAYMENTS: http://go.cms.gov/openpayments


Please visit DJO’s Sunshine site at http://djoglobal.com/compliance/sunshine

### What is the Compliance Timeline on the Sunshine Law Requirements?

<table>
<thead>
<tr>
<th>Date</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug. 1, 2013</td>
<td>Manufacturers and GPOs are required to begin collecting information about payments, transfers of value, and ownership interests.</td>
</tr>
<tr>
<td>Mar. 31, 2014</td>
<td>First manufacturer / GPO report is due. This report must cover August – December 2013 payments/transfers of value and ownership interests. Subsequent reports will cover an entire calendar year and be due the 90th day of the following year.</td>
</tr>
<tr>
<td>Aug. 2014 (in subsequent years, during the month of May)</td>
<td>Physicians and teaching hospitals may access their own data via secure online portal for review and correction.</td>
</tr>
</tbody>
</table>
| - 45 Days to Review and Initiate Disputes  
- 15 Days to Resolve Disputes | |
| Sept. 30, 2014 | 2013 data published on a public website by CMS. In subsequent years, information will be published on June 30. |

### Who is Required to Report?

- Manufacturers of medical devices, drugs, biologicals, and medical supplies operating in the United States, including certain wholesalers/distributors and certain entities under common ownership (3% or more) with a Manufacturer (collectively, “Manufacturers”) must submit Transparency Reports annually to CMS on Payments / Transfers of Value to Physicians and Teaching Hospitals;
- Group Purchasing Organizations (GPOs) and Manufacturers must report ownership and investment interests held by Physicians or their Immediate Family Members and any Payments / Transfers of Value to Physician Owner/Investors;
- Manufacturers must report ownership and investment interests held by Physicians or their Immediate Family Members, in GPOs and Manufacturers– the Dollar Amount Invested and the Value and Terms of the ownership or investment interest (excluding interests in publicly traded securities or mutual funds).
- Any Payments / Transfers of Value provided to the Physician owner or investor.

### What Must be Reported?

- Payments, Transfers of Value, and Ownership / Investment Interests held by Physicians or their Immediate Family Members, in GPOs and Manufacturers–
  - Direct payments and transfers of value
  - Indirect payments and transfers of value; and
  - Payments and transfers of value that are made to a third party at the request of or on behalf of a Teaching Hospital.

### What are the Nature of Payment Categories that must be used to describe Payments and Transfers of Value?

The Payment/Transfer of Value must be categorized as one of the following:
- Consulting fee;
- Compensation for serving as faculty or as a speaker for an accredited or certified CE program;
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified CE program;
- Compensation for services other than consulting, including serving as faculty at an event other than a Continuing Education (CE) program;
- Honoraria;
- Gift;
- Entertainment;
- Food and beverage;
- Travel & lodging (including specifying the destination);
- Education;
- Research;
- Charitable Contribution;
- Royalty or License;
- Ownership or Investment Interest (Current Prospective); and
- Grant;
- Space rental or facility fees (Teaching Hospital only).

### Can Teaching Hospitals Review the Data and Make Corrections, if necessary?

Before information is publicly posted, a Teaching Hospital will have 45 days to Review submitted data and Initiate Disputes once access to its own data is made available by CMS on a secure online portal. If the dispute is not resolved during this 45 day period, an additional 15 days are provided to come to a resolution. If the dispute continues, the data will still be posted to the public webpage but will be flagged as Disputed.

Teaching Hospitals are also able to seek correction or contest reports for two years after access has been provided to a report with disputed information.

### Where to Report Disputes?

- Physician Disputes: OPEN PAYMENTS: http://go.cms.gov/openpayments
- GPO Disputes: OPEN PAYMENTS: http://go.cms.gov/openpayments

### Who is Required to Report?

- Manufacturers of medical devices, drugs, biologicals, and medical supplies operating in the United States, including certain wholesalers/distributors and certain entities under common ownership (3% or more) with a Manufacturer (collectively, “Manufacturers”) must submit Transparency Reports annually to CMS on Payments / Transfers of Value to Physicians and Teaching Hospitals;
- Group Purchasing Organizations (GPOs) and Manufacturers must report ownership and investment interests held by Physicians or their Immediate Family Members and any Payments / Transfers of Value to Physician Owner/Investors;
- Manufacturers must report ownership and investment interests held by Physicians or their Immediate Family Members, in GPOs and Manufacturers– the Dollar Amount Invested and the Value and Terms of the ownership or investment interest (excluding interests in publicly traded securities or mutual funds).
- Any Payments / Transfers of Value provided to the Physician owner or investor.

### What Must be Reported?

- Payments, Transfers of Value, and Ownership / Investment Interests held by Physicians or their Immediate Family Members, in GPOs and Manufacturers–
  - Direct payments and transfers of value
  - Indirect payments and transfers of value; and
  - Payments and transfers of value that are made to a third party at the request of or on behalf of a Teaching Hospital.

### What are the Nature of Payment Categories that must be used to describe Payments and Transfers of Value?

The Payment/Transfer of Value must be categorized as one of the following:
- Consulting fee;
- Compensation for serving as faculty or as a speaker for an accredited or certified CE program;
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified CE program;
- Compensation for services other than consulting, including serving as faculty at an event other than a Continuing Education (CE) program;
- Honoraria;
- Gift;
- Entertainment;
- Food and beverage;
- Travel & lodging (including specifying the destination);
- Education;
- Research;
- Charitable Contribution;
- Royalty or License;
- Ownership or Investment Interest (Current Prospective); and
- Grant;
- Space rental or facility fees (Teaching Hospital only).

### Can Teaching Hospitals Review the Data and Make Corrections, if necessary?

Before information is publicly posted, a Teaching Hospital will have 45 days to Review submitted data and Initiate Disputes once access to its own data is made available by CMS on a secure online portal. If the dispute is not resolved during this 45 day period, an additional 15 days are provided to come to a resolution. If the dispute continues, the data will still be posted to the public webpage but will be flagged as Disputed.

Teaching Hospitals are also able to seek correction or contest reports for two years after access has been provided to a report with disputed information.
Generally, no, these would not need to be reported (e.g., a meal).

Non-physician employees of a Teaching Hospital are not covered recipients for the purposes of Open Payments. Accordingly, payments or other transfers of value made to these non-physician employees generally do not need to be reported.

Transfers of Value to Non-Physician Employees would need to be reported if:

1. The payments were made to the non-physician employee at the request or by direction of the Manufacturer on behalf of a covered recipient Physician or Teaching Hospital [pursuant to §403.904(a) and (c)(10)]
2. They were in fact Indirect Payments to a covered recipient Physician or Teaching Hospital being made through the non-physician employee [as defined at §403.902];
3. Indirect payments or other transfers of value occur when an applicable manufacturer or GPO requires, instructs, directs, or otherwise causes a third party to provide the payment or other transfer of value, in whole or in part, to a covered recipient.
4. Ex - a Manufacturer providing equipment to a non-physician employee of a Teaching Hospital that is intended to benefit the Teaching Hospital is considered an indirect payment to the Teaching Hospital.

See CMS FAQ8272 at: http://go.gov/dGtue

Are payments from a Manufacturer to a Teaching Hospital in order to purchase products or materials considered reportable under Open Payments?

Yes. There is no reporting exclusion for payments made to covered recipients for the purpose of purchasing products or materials.

See CMS FAQ8374 at: http://go.gov/JyjDP

What are the Penalties for Non-compliance?

Reporting incomplete or inaccurate information has the potential to mislead patients and other stakeholders and damage the reputation of manufacturers, physicians and teaching hospitals.

Depending on the circumstances, non-compliance with the Sunshine Law’s reporting requirements could subject a manufacturer to financial penalties ranging from:

1. $10,000 to $100,000 for each payment or transfer of value not reported;
2. $10,000 to $100,000 for “knowingly” failing to report a payment or transfer of value.

The total maximum penalties which may be imposed against a Manufacturer or GPO is $1,150,000 per year.

What Payments/Transfers of Value are excluded from reporting?

Payments /Transfers of Value that are:

1. For Speaking at a Continuing Education Program if 3 Conditions are met:
   a) Program meets accreditation / certification requirements and standards of ACCME, AOA, AAMA, AAFP or ACPERP;
   b) The manufacturer does not select the speaker and does not provide a distinct, identifiable set of individuals to be considered as speakers; and
   c) The manufacturer does Not Directly Pay the Physician speaker.
2. From Existing Personal Relationships (e.g., one spouse who works for a manufacturer giving a gift to their spouse who is a Physician).
3. Less than $10 when the total value for the year is less than or equal to $100 (This amount to be adjusted beginning 2014 with the consumer price index)
4. Educational Materials that Directly Benefit Patients or are Intended For Patient Use such as patient education materials and anatomical models, but excluding journal articles and textbooks.
5. Discounts and Rebates
6. In-Kind Items for the Provision of Charity Care.
7. Product Samples (including coupons and vouchers) where there is an agreement in writing that the products will be provided to patients.
8. Evaluation/demonstration units – of 90 days or less average daily use.
9. Items and Services Provided Under a Contractual Warranty, Service or Maintenance Agreement
10. Received by the Physician as a Patient (e.g., Product Samples, Coupons, or Vouchers or as a subject in a research study)
11. For the Provision of Healthcare Services provided to a manufacturer’s employees or their family (e.g., on-site clinical services);
12. For Licensed Nonmedical Professional Services (e.g., a physician-attorney paid only for legal services); and
13. For services with respect to a Civil or Criminal Action or Administrative Proceeding (e.g., as an expert witness)

Value of Industry-Provider Collaborations

Collaboration and interactions between medical technology companies and health care providers are essential to advancing new, safe and effective medical technologies that benefit patients. AdvaMed recognizes that this goal must be balanced against the obligation of health care providers to make independent decisions regarding the care and treatment of their patients. AdvaMed and its member medical technology companies are committed to transparency with patients about interactions between providers and industry.