The Final Rule of the Physician Payment Sunshine Act – Section 6002 of the Patient Protection and Affordable Care Act requires applicable manufacturers of covered drugs and devices to report payments made to covered recipients to the Secretary of Health and Human Services. The Final Rule contains highly technical definitions and complex reporting requirements and exclusions. Below is a reference guide to provide short definitions and condensed reporting requirements to help you understand whether a payment falls within the scope of the Act.

IMPORTANT DATES
- Start date for collection of information - August 1, 2013
- Registration for CMS Review Site – January 1, 2014
- Manufacturer report date to CMS - March 31, 2014
- CMS publication date - September 30, 2014 and June 30th in future years

DEFINITIONS
Applicable Manufacturer: An entity that is engaged in the production of a covered drug, device, biological, or medical supply, but not if such covered item is solely for use by or within the entity itself or by the entity’s own patients. The applicable manufacturer is the reporting entity.

Covered Product: Covered drug, device, or medical supply as “any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid or CHIP and require a prescription or premarket approval by or notification to FDA. OTC drugs and devices are not included in this definition.

Covered Recipient: Any physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or a teaching hospital, any hospital receiving direct or indirect graduate medical education funding.

Payments of Transfers of Value: Transfer of anything of value where value is defined as “the discernible economic value on the open market in the United States” regardless of whether or not the item has value to the covered recipient. There are a number of payment exclusions, please consult the final rule for a comprehensive list. The rule provides specific accounting requirements for meals provided to covered recipients at dinners, conferences and at the covered recipient’s place of business.

Indirect Payments: A payment that an applicable manufacturer requires, instructs, or directs to be provided to a covered recipient, regardless of whether the applicable manufacturer specifies the specific covered recipient. Indirect payments are excluded from reporting in situations where the applicable manufacturer does not “know” the identity of the covered recipient or is unaware of the payment.

REPORTING REQUIREMENTS
A report will include: 1) The name of the applicable manufacturer; 2) covered recipients name, specialty, practice address, National Provider Identifier, and state licensing number; 3) amount and date and form of payment; 4) nature of payment; 5) name of covered product; and 6) name of receiving entity if covered recipient directs the payment to a third party.

PAYMENTS FOR RESEARCH
Payments for research are reported under a different template. Research reports must include 1) the identity of the entity paid; 2) the name of the principal investigators; 3) the total amount of the payments; 4) the name of the study; and 5) the name(s) of the related covered drug, device, biological or medical supply and National Drug Code. Research reporting for product development or clinical investigations for new products can be delayed in order to maintain confidentiality for proprietary information relating to the development of new drugs and devices.

CME EXCLUSION
Payments for continuing medical education are excluded from reporting requirements where 1) the program meets the accreditation or certification requirements and standards of ACCME, AOA, AMA, AAFP, or ADA CERP; 2) the covered recipient is not selected by the applicable manufacturer nor does the applicable manufacturer provide the third party a set of individuals to be considered as speakers; and 3) the covered recipient speaker is not directly paid by the applicable manufacturer.

PHYSICIAN REVIEW PERIOD
Once a covered recipient is included in a report by an applicable manufacturer they will be given a 45 day review period to confirm the data provided in the review. At the conclusion of the review period the applicable manufacturer is provided 15 days to correct any disputes made by the covered recipient. CMS will not moderate disputes.