I. Definitions

A. Covered Recipients

1. Physicians

Any physician holding an active state license is a covered recipient, and payments or other transfers of value to physicians must be reported. CMS stated that payments and transfers of value provided to residents and to employees of the reporting manufacturer are not covered by the final rule (whereas payments and transfers of value provided to a physician employee of another company are reportable). Board members, prospective employees, and retirees of manufacturers are excluded from reporting only to the extent that they meet the IRS definition of “employee,” referenced in the statute, with respect to the manufacturer that made the payment.

Manufacturers will need to report the physicians’ National Provider Identifiers (NPIs), and should use the National Plan & Provider Enumeration System (NPPES), which CMS maintains on its website, to identify physicians’ NPIs. CMS added that the NPI used for each physician must be the individual NPI (rather than a group NPI). As set forth in the statute, NPIs will not be published on the public website.

If the physician’s NPI is not in the NPPES, the manufacturer is responsible for obtaining the physician’s individual NPI number directly from the physician. Manufacturers must make a good faith effort to obtain an NPI for the physician, including by specifically requesting an NPI from the physician, checking the NPPES database, and calling the NPPES help desk. Manufacturers may rely on NPI information in the NPPES as of 90 days before the beginning of the reporting year. If a manufacturer cannot, after a good faith effort, determine a physician’s NPI, the manufacturer may leave the NPI field blank. However, if CMS later determines that a physician covered recipient does have an NPI, the agency may require the manufacturer to re-submit the data, including the NPI, and re-attest to the updated data. Moreover, the report may be considered inaccurate and the manufacturer subject to penalties.

CMS also stated that manufacturers must report at least one state license number for all physicians, regardless of whether the manufacturer is also reporting an NPI for a particular physician.

Manufacturers must report the physician’s specialty, using their internal information about the physician’s specialty, but they should use the
NPPES provider taxonomy list as the list of accepted specialties to ensure consistency in the names of reported specialties.

Manufacturers must report the physician’s name as it appears in the NPPES. For the business address, manufacturers should report the physician’s primary business address, if possible, including a street address.

2. Teaching Hospitals

Teaching hospital covered recipients are hospitals that receive a payment under the Medicare direct GME or IME programs. In the final rule, CMS stated that it will publish the list of teaching hospitals once annually and make the list available at least 90 days before the beginning of each reporting year (at least 90 days prior to the start of data collection for the first reporting year). Manufacturers will be able to rely on the list for the entire data collection year.

B. Manufacturer

A manufacturer that has to report is a manufacturer operating in the United States that is (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 and distribution in the United States, or in a territory, possession, or commonwealth of the United States.

Manufacturers of raw materials for prescription drugs are not covered by the statute and are not required to submit reports. Likewise, hospitals, pharmacies, and laboratories that produce or manufacture materials and products solely for their own use or use by their patients are not covered by the statute and are not required to submit reports. On the other hand, distributors, wholesalers and repackagers that hold title to a prescription drug or medical supply are covered and required to report.

When a manufacturer has several subsidiaries that operate somewhat independently, or if two manufacturers are owned by another company, the various companies can choose to report separately or under one company name. If one company files a single report for several subsidiaries, for example, the reporting company must specify the name of the company that actually made the payment or transfer of value. Presumably, when physicians look at the pre-public report during the review period, and when anyone looks at the public report, they will see the
payment or transfer of value associated with the name of the company that actually made the payment or transfer of value.

C. **Covered Drug, Device, Biological, or Medical Supply**

In the final rule, CMS clarified that a product is covered if payment is available for the drug under Medicare, Medicaid, or CHIP and the drug requires a prescription (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a device or a medical supply that is a device). The final rule also stated that covered products are those that are reimbursed separately as well as those that are reimbursed as part of a bundled payment.

Manufacturers of both covered drugs, biologics, medical supplies (prescription products) and non-covered products (such as over-the-counter drugs, animal health drugs, and consumer products) must report all payments or transfers of value to covered recipients, whether or not the payments are associated with a covered product (the “all-in” rule).

In the final rule, CMS said that manufacturers with less than 10 percent of total (gross) revenues from covered products during the previous fiscal year may report only payments or other transfers of value specifically related to covered products. These manufacturers must attest in their submission that less than 10 percent of their total (gross) revenues are from covered products.

CMS also stated that manufacturers that have separate operating divisions that produce only non-covered products and do not meet the definition of providing “assistance and support” to the manufacturer of a covered product must report only payments or other transfers of value made by that separate operating division that are related to a covered product.

As a result, some companies that physicians view as manufacturers of OTC medicines, consumer products, or animal health products might have their payments or transfers of value to physicians reported to CMS directly by that company or by their parent or sister company because of the corporate relationship between the two companies.

In the final rule, CMS stated that manufacturers must report a related product for all payments or transfers of value, unless the payment or other transfer of value is not related to a covered product. For payments and transfers of value not related to at least one covered product, manufacturers should report “none.” Conversely, for payments and transfers of value related to a specific product that is not a covered product, manufacturers should report “non-covered product.” For payments and transfers of value related to both a covered product and a non-covered product, manufacturers should report the covered product by name and
may include the non-covered product in one of the fields for reporting associated products.

CMS further allowed manufacturers to report up to five covered products associated with each payment or transfer of value. When aggregating payments or other transfers of value by product, CMS will not represent a single interaction related to multiple products as multiple interactions. For drugs and biologicals, manufacturers must report the market name of the product and must include the NDC (if any). If a market name is not yet available, manufacturers should use the name registered on clinicaltrials.gov.

II. Report Content

In the final rule, CMS outlined the required information to be included in reports of payments or transfers of value. For each payment and other transfer of value, the report must include:

- Applicable manufacturer’s name;
- Covered recipient’s (1) name, (2) specialty, (3) primary business street address, (4) NPI, and (5) state professional license number(s) for at least one state where the physician maintains a license, including the applicable state where the license is held;
- Amount of payment or other transfer of value;
- Date of payment or other transfer of value;
- Form of payment or other transfer of value;
- Nature of payment or other transfer of value;
- Name(s) of the related covered product, as applicable;
- NDCs of related covered drugs and biologicals, if any;
- Name of entity that received the payment or other transfer of value, if it was not directly provided to the covered recipient;
- A “yes or no response” to whether a payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer; and
- Statement providing additional context for the payment or other transfer of value (optional).
For each research-related payment or other transfer of value the report must include:

- Applicable manufacturer’s name;
- Name of research institution/entity receiving payment;
- Total amount of research payment;
- Name of study;
- Name(s) of related covered drug, device, biological or medical supply;
- NDCs of related covered drugs and biologicals, if any;
- Principal investigators, including name, NPI, state professional license number(s) for at least one state where the physician maintains a license including the applicable state where the license(s) is held, specialty, and primary business address;
- Context of research (optional);
- ClinicalTrials.gov identifier (optional); and
- “Yes or no Response” to question of whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation.

III. Exclusions from Reporting

The statute excludes certain types of payments and transfers of value from reporting. CMS declined to adopt additional exclusions, but provided additional information to clarify its interpretation of the exclusions.

A. Existing Personal Relationships

CMS stated that payments associated with existing personal relationships do not require reporting.

B. Payments or Other Transfers of Value of Less than $10

CMS stated that the final rule will allow flexibility in reporting small payments or transfers of value. A manufacturer may report small payments and transfers of value either individually or combined with other small payments and transfers of value that are in the same nature of payment category. Manufacturers
must use their chosen method of reporting consistently and clearly designate the method of reporting that they use. The de minimis reporting thresholds will stay the same throughout an entire reporting period, but CMS will increase the de minimis thresholds by the Cost of Living Index for each year beginning with the 2014 data collection period.

The final rule also states that small incidental items valued at less than $10 (such as pens and notepads) provided at conferences and at events that are open to the public can be excluded from reporting and need not be aggregated with other small payments and transfers of value.

C. Educational Materials that Directly Benefit Patients or Are Intended for Patient Use

In the proposed rule, CMS stated that the exclusion for educational materials that directly benefit patients or are intended for patient use is limited to “materials” and does not include services or other items. PhRMA requested clarification from CMS as to whether and how educational materials intended for ultimate patient use and items and materials provided in the context of a clinical trial should be designated as transfers of value to covered recipients.

In the final rule, CMS excluded educational materials that directly benefit patients or are intended for patient use, and CMS stated that “materials” are not limited to written materials, but may take other forms. CMS also stated that overhead expenses, such as printing and time preparing these materials, are covered by the exclusion, provided they are “directly related” to producing materials that “directly benefit patients or are intended for patient use.”

CMS further explained that the provision of educational materials that “are educational to covered recipients (such as medical textbooks and journal reprints), but are not intended for patient use” do not fall within the statutory exclusion, even though these materials have downstream benefits for patients.

D. Product Samples

In the final rule, CMS stated that the product sample exclusion includes a drug, device, biological, or medical supply that a covered recipient receives for use by patients. Coupons and vouchers intended to minimize the cost of drugs, devices, or biologicals also fall within the exclusion. Products used for research should be included in the larger research payment.

E. Provision of Healthcare

This exclusion applies to “payments to covered recipients for services rendered to family members” who receive care through a self-insured plan and to
other situations when a manufacturer makes a payment to a covered recipient for health care services provided to the manufacturer’s employees or family members (e.g., an on-site clinic or health care).