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Dear Sunovion Colleagues:

At long last, we finally have Sunshine Act regulations in place to govern Aggregate Spend Reporting. The regulations were issued on February 1, 2013 and after carefully analyzing the 276 page document, we are presenting you with important information that affects you and your Investigators / Doctors. Note that this is only a preliminary announcement. There will be additional communications and discussions over the coming weeks and months to assure that everyone in R&D is fully informed about these important new regulations.

The Center for Medicare & Medicaid Services (CMS), part of the FDA, has published regulations and draft reporting templates. CMS has promised further clarifications as pharmaceutical and medical device companies raise questions. However, we believe the "rules" are basically settled at this point.

Here are the main points:

- The year one Tracking period begins on August 1 running to December 31, 2013 and on a calendar basis thereafter.
- Only MDs and DOs are "covered recipients" (NPs and PAs are not included for Federal reporting)
- Sunovion reports all spend to Center for Medicare and Medicaid Services (CMS) by March 31, 2014
- Any "transfer of value" to a covered recipient" must be reported
- MDs and DOs have 45 days to dispute amounts reported by Sunovion
- Sunovion has an additional 15 days to work out disputes with "covered recipients" and either correct or confirm amounts reported by Sunovion
- CMS totals spending by "covered recipient" (MD/DO) and publishes the results by September 30, 2014

Sunovion has an Aggregate Spend Steering Committee comprised of representatives from all parts of the organization. This Steering Committee has met on a number of occasions over the past two years reviewing and preparing for Transparency reporting. In addition, we are already working with the Clinical Trial Management System (CTMS) team to make sure this system will capture

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necessary Transparency information. One goal of working closely with the CTMS team is to assure that we have identified all MDs and DOs and any other reportable "covered recipients" (Dentists, Podiatrists, Optometrists and licensed Chiropractors) paid by Sunovion or paid indirectly for Sunovion via a third party (e.g., a CRO). Other attendees at Sunovion sponsored events (e.g., investigator meetings, site visits) need to be documented including full name and credential. The US government takes the position that "if it is not recorded when the event occurred, then it did not happen" so accurate documentation of attendees recorded in Concur and/or Veeva is critical. Every error or omission can result in a fine of between $1,000 to $10,000 dollars.

FAQs

Below are a number of FAQs for which we have provided the best available answer but because there is not much precedent for Transparency reporting on Clinical/R&D efforts. We expect there will be additional sub-guidance issued by CMS

What does this mean for Sunovion employees in Clinical Research, Research and Development, AMS, HEOR or Medical Affairs staff who have interactions with MDs and DOs and how do we comply with this law?

Transactions such as a lunch or dinner with a MD/DO which are normally recorded in Concur also need to be sure to reflect their proper medical credentials. For the AMS and HEOR field based staff, recording these transactions in Veeva is important to accurate reflect activities and record them at the time they occur when the details are fresh in your mind.

Others transactions such as providing a journal reprint or assistance to an MD authoring a journal article are also considered by FDA as reportable transactions. Valuing these types of transactions involves legal interpretations of the regs which has begun but will need to be a collaborative process between you and the Aggregate Spend team to make sure these transactions are captured.

How are transfers of value arising from Advisory Boards, Investigator meetings, Protocol / Rater review meetings allocated to the participating Investigators/ attendees?

FDA/CMS has indicated that payments for airfare, hotel needed to be tracked at an individual covered recipient level whereas meals and snacks would be allocated based on the expected /planned for number of attendees. The implication is that a meeting designed for 20 individuals where only 16actually attend will not be allocated the cost of meals for the "no show" invitees. However, the "no shows" invitees would most likely have any non-refundable airfares reported as a transfer of value to them.

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Is every payment made by Clinical or R&D considered "research"?

Not necessarily. The regs require a written research protocol or contract to qualify as research and be subject to the "deferred reporting" for research activity otherwise these transfers of value would be reported in that year's filing.

Will payments to investigators be lumped in with payments by the Sunovion Commercial organization?

It depends. CMS produced two templates for reporting companies to complete, one for Research and one for all other transactions (primarily Commercial) but MDs serving as consultants not meeting the "research" requirements would be reported on the second (Commercial) template.

Will Sunovion use the deferred reporting option for Clinical Trial spending?

Probably. Legal and Compliance will present the options to the Aggregate Spend Steering Committee (and ultimately the ELT) after Legal makes an evaluation of the regs.

What is a Teaching Hospital?

On May 3, 2013 CMS produced a list of 1,162 institutions that the agency designated as a "teaching hospital". The list can be found at:

http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/

What is the difference between a direct and an indirect research payment?

A direct payment is one where the transfer of value was made to a covered recipient by Sunovion or its agent. An indirect payment is where a transfer of value may be made to an institution not directly to the Principal Investigator. The intent of the regulations is to require reporting on transfers of value to "covered recipients" regardless of the structure / process.

How are MDs and DOs clearly identified?

CMS has mandated that the covered recipient's National Provider Identifier number will be reported along with a state license number used which covers the vast majority "Covered Recipients".

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When does "payment" to a "covered recipient" occur?

The regulations provide a "reporting" company with some latitude for selecting a "payment date" methodology but CMS require us to apply the methodology for designating a payment date consistently for similar transactions. A few common examples are the payment date would generally occur when a payment is made to a consultant or investigator or the date of a dinner or lunch event.

Do these regulations apply to US licensed doctors practicing outside of the US?

The Sunshine Act pertains to US licensed MDs and DOs no matter where they practice medicine.

Do these regulations apply to non US licensed doctors?

The Sunshine Act pertains to only US licensed MDs and DOs. However many other countries (e.g. Japan, UK, France et al.) have existing or proposed transparency regulations for MDs and DOs practicing in those countries.

Is there a place to submit questions we may have?

Yes, please send your question regarding Aggregate Spend reporting to Aggregate.Spend@Sunovion.com and we will respond as promptly as possible but please recognize that the answer may take time to resolve. We will also periodically publish additional FAQs to the Clinical Trial and R&D team.