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Dear Field Sales 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 both and your 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 Field Sales is fully informed about these important new regulations.

The Center for Medicare & Medicaid Services (CMS), part of the FDA, has published regulations and accompanying 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 by March 31, 2014
- MDs and DOs have 45 days to dispute reported amounts.
- Sunovion has 15 additional days to work out disputes with “covered recipients”
- CMS totals spending by “covered recipient” (MD/DO) and publishes the results by September 30, 2014

Frequently Asked Questions

What does this mean for Therapeutic Specialists (TS) and how do we comply with this law?

TSs need to perform two main tasks:

- 1. Conduct compliant Speaker Programs and submit all documentation timely so we can get the data processed quickly and identify questions promptly. Plan and execute your programs with the expectation that they WILL BE scrutinized by OIG/DOJ auditors/attorneys.*
- 2. Input all Lunch & Learn (LnL) events into Veeva accurately (exact \$ amounts matching what will appear on the AMEX bill) and most importantly input all attendees into Veeva with full first name, last name, middle initial (when available), and medical credentials.*

In the near future, we will be working with the Veeva team to develop a drop down box of acceptable medical credentials. The goal is to identify all MDs and DOs and any other reportable “covered recipients” (Dentists, Podiatrists, Optometrists and licensed Chiropractors). Other attendees need to be documented including full name and credential (with the default being Medical Assistant). The 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 Veeva is critical. Every error or omission can result in a fine of between \$1,000 to \$10,000 dollars.

How does the cost get allocated to the “Covered recipient”?

For a \$100 Lunch and Learn (LnL) event with two MDs and four nurses, two MAs and the receptionist (9 individuals) plus the TS for 10 people, the cost allocated to the two MDs is \$10 each.

What happens if the office tells me to bring sandwiches/food for eleven people (totaling of \$100) and only five show up?

There will be occasions when there is a poor turnout and the allocation would be based on the expected number of attendees so in this situation it would be \$100/12 (eleven people plus the TS) or \$8.33 reported per “covered recipient”. Accordingly, you should review prior LnLs at that office and determine the most typical level of attendees expected if the office manager “overestimates” the number of attendees. Any leftover food would be considered a reportable “gift” so you should err on the side of less, not more in planning LnLs. In these cases you may not want to eat if there is an unexpected higher turnout.

What happens if I hold a LnL and no doctors show?

This should be an extremely rare occurrence because LnLs are scheduled but when it occurs, please record a note in Veeva that the doctor did not show.

What if I have an clinic headed by an NP and there are no “covered recipients” practicing in that office?

The LnLs in that office would not be reported under the Sunshine Act, however the documentation requirements and Business Courtesies policy still apply.

Does the current PhRMA code and Company policy for Business Courtesies exclude the receptionist (a non HCP – not involved in patient care) and TS in determining who “counts” for the \$25 per HCP limit?

We have discussed this issue with PhRMA who will consider the conflict soon and we will revisit the need to update the Business Courtesies policy. However, most MDs and DOs are likely to understand holding down the LnL costs to minimize the amounts reported for them.

Will you be issuing a communication to the MDs and DOs soon?

Yes, we have also developed a letter to provide to a MD/DO if they request one to help educate and clarify the implications of the new law.

What about text books, brain models, reprints, co-pay cards and drug samples?

There is mixed news here:

Items used in patient education are exempt from reporting requirements but CMS explicitly said textbooks for doctors and reprints WERE subject to reporting.

Co-pay cards and drug samples are not included in the Sunshine Act Aggregate Spend reporting but drug samples by “prescriber” by location must be reported annually under a different section of the Patient Protection and Affordability Care Act (PPACA).

How will meals, beverages and other costs at a Speaker Program be allocated to attendees?

The CMS regulations did not address this specific type of transaction. The legal interpretations of the law is that the “planned amount of the cost per meal plus beverages, tax and tip would be

allocated among all who partook of the meal. For example, below are the details of a complicated, real life situation:

For Speaker Programs with the following assumptions:

- restaurant requires a minimum guarantee of \$1,000
- a contracted \$75 per plate dinner for 10 attendees (5 MDs and 5 others e.g. NP, PA or RNs) plus the Therapeutic Specialist and speaker (total 12 attendees expected or food of $12 * \$75 = \900)
- beverages in addition to meal costs (expected ~ two glasses of wine per attendee $10 * 2 * \$5 = \100)
- tip and taxes of 25% or (\$250 tip/tax) for total meal, beverage, tip and tax of \$1,250
- audio/visual costs of \$100 and
- a facilitator to check in attendees / obtain signatures (cost of \$150)

The allocation is \$1250/12 or ~\$104.17 will be reported per “covered recipient” i.e. the five doctors (and also the Speaker who is typically and MD) will each have \$104.17. None of the A/V costs, facilitator fee, room or unmet guaranteed minimum charges are allocated to any attendee based on our current interpretation of the law.

So what happens when only 6 attendees show up (plus Therapeutic Specialist and speaker) and the restaurant minimum guarantee kicks in?

- *Is the cost per person based on planned cost (\$105 / person) or actual costs (\$1,000/8 = \$125.00 per person?*

The cost allocated to covered recipients is still \$104.17 each.

Is there a place to submit questions we may have?

Yes, please send your question regarding Aggregate Spend reporting and Drug Samples 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 Field Sales team.

How will you resolve disputes with MDs and DOs over the reported amount?

We are exploring a feature on the Sunovion HCP portal where the doctor can log in and see his total and the detailed transactions similar to any “frequent flyer” website. This is where it is critical that TSs input LnL event and Speaker Program data timely.

What if my Key Opinion Leaders (KOLs) are also involved in Clinical Trials, Advisory Boards or consult for Sunovion?

Any and all items of value must be reported under the Sunshine Act including Speaking fees, consulting fees, travel and meals expenses which must be lumped in with LnL and Speaker Program meals.

R&D / Clinical Trials have a different reporting format and will NOT be lumped in with the above total. CMS will be publishing R&D/Clinical Trials spend in a separate section of their website.

What is a “Teaching Hospital” and how will these transactions be reported?

A “Teaching Hospital” is defined under the law and CMS has published a list of them. Any payments made to a “Teaching Hospital” must be reported depending on the nature of the payment.

What if a doctor does not want to be “reported”, can I still bring coffee or donuts?

There is a provision in the regulations that if every meal is <\$10 AND it is less than \$100 for the year, we do not need to report the doctor. We still need to track the spending but in preparing the disclosure report, these doctors would be eliminated. However even if the spend on even one LnL spend amount reaches \$10 per person or more, the “covered recipient” must be reported (even if the annual \$100 threshold is not reached). TSs in Minnesota and Vermont already operate under even tighter restrictions.

Does this change the expense receipt requirement?

Very likely. We are re-evaluating the current practices and may need to require all receipts be provided to document the coffee and donuts as well as lunches. You will receive further notice when we reevaluate the Business Courtesies policy and Sales Operations SOPs.

Must I enter the attendees in Veeva or can I use Concur?

You MUST enter all attendees in Veeva. The Veeva system provides excellent timely detailed records of calls we export into the Aggregate Spend system. Concur is not capable of providing the necessary level of detail. Also, TSs input Concur expense reports once or twice a month well after the LnLs occur so the reliability of the attendee data would be questioned by a government auditor.

Can the doctor opt out of the Lunch & Learn?

No, this would result in a gift to the doctor of the entire amount of the LnL so they must agree to their allocation.

Can a doctor “pay his/her own way” or otherwise opt out of a Speaker Program meal?

Yes, this is possible but the doctor must inform us when they register so we do order the current number of meals.

Can I wait for the weekend to enter my LnL calls for the past week?

No, these LnL events should be recorded as close to the time they occur. Events entered days or weeks later would appear suspicious to an OIG auditor and cast doubt regarding whether the TS recalled correctly all the attendees. Get in the habit of entering all call daily and synching you tablet each night.

Do we need paper sign in sheets for Lunch and Learns?

No, the preferred method is to enter the entire office roster in Veeva and “click” on those that attend the event which can then be attached to the Concur expense report. The advantage is this document is legible but the disadvantage is the TS needs to do some level of maintenance to keep a current roster of who leaves and joins the practice. In a limited set of circumstances such as an event at a hospital where you do not have a roster of the individuals, one alternative to use is a paper sign in sheet (which must be complete and legible so the TS can then enter the attendee into the Veeva system at the completion of the event). The paper sign in sheet can then be scanned in when preparing the Concur expense report.

Do I need to do anything new or different regarding the Doctor’s NPI # or state license #?

No, Compliance, Commercial Operations and IT have been working over the past year to link Sunovion I.D. to NPI number and state license number(s) so this is already in place.

Does this change any of the state reporting aggregate spend obligations?

This is still unclear but the law states that the states may not request the same data required under the Sunshine Act. For the TSs in those states where these laws are modified or repealed, we will provide specific guidance.

Relevant Sections of the Business Courtesies Policy 3.05:

2.7 "Healthcare Professional or HCP" refers to: (a) physicians, physician assistants, nurses, nurse practitioners, pharmacists, medical assistants, and other medical professionals involved in patient care, (b) scientists or others who, because of their professional reputations may have an influence on clinical opinions, even though they would not be prescribing pharmaceutical products, and (c) others who can influence the purchase and/or prescribing of Sunovion products, including group purchasing organizations, pharmacy benefit managers, managed care organizations, and other entities who arrange for the provision of healthcare services, such as, home healthcare agencies.

4.5 In connection with approved promotional activities, including informational presentations and discussions with HCPs, Field Sales Representatives and/or their immediate managers may provide **modest, occasional** meals to HCPs if such meals: (1) are modest as judged by local standards, not to exceed \$25 per person; (2) are limited to in-office or in-hospital settings; (3) are not part of any Entertainment; and (4) the meal is provided in connection with approved promotional activities, including informational presentations and discussions. Except as otherwise permitted pursuant to this Policy, Field Sales Representatives and/or their Immediate Managers are prohibited from providing meals to an HCP outside of the in-office or in-hospital setting. No Entertainment maybe provided to Healthcare Professionals.

5.3 Failure to Comply

EMPLOYEES WHO VIOLATE ANY SUNOVION POLICIES AND PROCEDURES WILL BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.