



Sunovion Pharmaceuticals Inc.

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Dear Doctor:

Sunovion Pharmaceuticals Inc. is providing this letter to update you on the recently issued Sunshine Act's Aggregate spend regulations. Sunovion is committed to transparency and compliance with this law. We conducted an in depth analysis of the Sunshine Act's regulations and consulted several experts to help clarify the implications for many of the common transactions involving interactions that you may have with Sunovion's Therapeutic Specialists. This letter is intended to summarize Sunovion's interpretation of those findings. This letter does not constitute legal or tax advice.

Below are the main points:

- The year one Tracking period begins on August 1 running to December 31, 2013 and on a calendar basis thereafter.
- MDs and DOs are "covered recipients" (NPs and PAs are excluded for Federal reporting).
- Sunovion will report all spend to Center for Medicare and Medicaid Services (CMS) by March 31, 2014.
- MDs and DOs have 45 days to dispute reported amounts.
- Sunovion has 15 additional days to resolve disputes with "covered recipients"
- CMS aggregates spending by "covered recipient" (MD/DO) and will publish totals by September 30, 2014

Frequently Asked Questions

(The examples below are meant to be representative of situations and transactions that may occur, but is not an exhaustive list.)

Who is a “covered recipient” under the regulations requiring disclosure of all transfers of value by pharmaceutical and medical device companies?

The regulations specify all Doctors of Medicine and Osteopathy, Dentists, Podiatrists, Optometrists and licensed Chiropractors. Nurse Practitioners, Physician Assistants and other health care professionals are excluded by these regulations.

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

For a \$99.90 Lunch and Learn event with two MDs and four nurses, two Medical Assistants and the receptionist (9 individuals) plus the Therapeutic Specialist for 10 people, the cost allocated to the two MDs is \$9.90 each.

What happens if the Therapeutic Specialist brings sandwiches/food for more than the number of HCPs in the office that day?

There will be occasions when the number of HCPs indicated by the office manager was higher than the turnout. The guidance we have received is that the allocation would be based on the expected number of attendees.

What about text books, brain models, reprints, copay cards and drug samples?

There is mixed news here:

Items used in patient education are exempt from reporting requirements but CMS explicitly stated that textbooks for doctors, and reprints, ARE subject to reporting.

Copay 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.

What if I accept a cup of coffee at a conference or convention?

CMS has exempted this type of interaction where it would not be reasonable to track and identify covered recipients.

How and when will Drug Sample transactions be reported?

Under Section 6004 of the Patient Protection and Affordability Care Act, Congress mandated pharmaceutical and medical device companies annually report samples provided to HCPs by location, drug and drug strength. This responsibility was assigned to CDER, a division within FDA. The regulations were very brief and industry has been awaiting further guidance which had delayed the 2011 filing. The 2012 Sample Reporting filing is due on March 31, 2014. We expect to file both years' data using reasonable assumptions if further guidance is not forthcoming.

Is there a place to submit questions I may have on how Sunovion plans to comply with specific aspects of the regulations?

Yes, please send your question regarding Aggregate Spend reporting or Drug Samples to Aggregate.Spend@Sunovion.com. We will respond as promptly as possible but please recognize that it may take time to analyze the regulations and answer your question.

How will Sunovion resolve disputes with MDs and DOs over the reported amounts?

We are exploring a feature on the Sunovion HCP portal where the doctor can log in and see their total and the detailed transactions similar to any “frequent flyer” website. We will update you on the progress in the next few months.

What if I am 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 Lunch and Learn 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 can I do to ensure accuracy of any reported data?

You should check your NPI listing on CMS's website <https://nppes.cms.hhs.gov> to make sure your name, address, state license(s), specialty/taxonomy are complete and accurate.

What if I do not want to be “reported”, can I still attend a Lunch and Learn event?

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 under \$100 and \$10 for each meal would be exempted from reporting. However even if the spend on even one Lunch and Learn spend amount reaches \$10 per person or more, the “covered recipient” must be reported (even if the annual \$100 threshold is not reached).

Can I opt out of the Lunch & Learn?

No, this would result in a “gift” to the doctor of the entire amount of the Lunch and Learn so they must agree to their pro rata meal allocation.

Can I “pay my 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 order the correct number of meals.

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

This is still unclear, but the Aggregate Spend law states that the states may not request the same data required under the Sunshine Act. For HCPs in those states that still have a requirement (MA, VT, WV, and Washington DC), we will continue to report as has been done in the past.

Does the Sunshine Act have any income tax impact on Lunch and Learn and Speaker Programs?

When Congress passed the Sunshine Act disclosure requirements as part of the PPACA bill (Section 6002), there were no provisions in this law to change any tax implications. Sunovion cannot provide tax advice to your organization. You should check your specific situation with your own tax/legal advisors, particularly if you are a state or Federal employee or subject to an institutional Code of Conduct provision that limits or prohibits accepting anything of value from a vendor.