



ONE FROM THE MIDDLE RBM Toolkit

Coaching Tools

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COACHING TOOLS

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Request for Product Information

Background

George, a Sunovion Therapeutic Specialist, has been calling on a target physician and after several months of sales calls, the physician began to prescribe the Sunovion product.

George also met with the Nurse Practitioner in the office. The Nurse Practitioner was hesitant to start any new patients, despite the target physician in the office starting several patients himself. George gave an overview of the product and seemed to think the Nurse Practitioner was interested. The Nurse Practitioner thanked George for the information and asked him for his business card.

Several days later, the Nurse Practitioner emailed George and asked him several clarifying questions, specifically on the dosing of the product, the managed care coverage and the cost of the medication. George was anxious to get the Nurse Practitioner onboard with prescribing the product and decided to reply to her questions by email. He thought it would be best to also include the prescribing information in his response.

EMAIL COMMUNICATION WITH HCPS

Request for Product Information

Question

- How should George respond to this email request?
- Was it appropriate to provide information on Sunovion's product by email, as well as the prescribing information?



EMAIL COMMUNICATION WITH HCPS

Request for Product Information

Acceptable Response ✓

Thank you for taking the time to meet with me several days ago. Due to the nature of the information, I am unable to send it to you via email. I would be happy to follow up on our conversation. Could we schedule a time in the next few days for me to return to your office and meet with you?

Unacceptable Response ✗

Here is an example of an unacceptable response.

Thank you for taking the time to meet with me several days ago. I can provide you some additional information. Most patients are covered under state and commercial plans and you should have no barriers for formulary coverage. It is important that you review the prescribing information before starting any patient. I have attached a copy for your review.

EMAIL COMMUNICATION WITH HCPS

Request for Product Information


Key Learning Points



- George did not handle this situation appropriately and should not have provided any product information by email, including sending a copy of the prescribing information.
- George should have promptly sent a message back to the Nurse Practitioner requesting a face-to-face meeting instead of sharing product information by email.
- If George felt this email was an urgent request for information due to a patient safety concern or adverse event, he could refer the HCP to the Sunovion Medical Information phone number.
- George's email should include a PMRC-approved trigger letter within the response.

Request for Product Information

Putting Policy Into Practice USE OF EMAIL AND TEXT

- 
- Email and texts can only be used to confirm appointments, lunch and learn details, and/or logistical requirements.
 - Email and texts may not be used to promote Sunovion products, including making any claims in the body of the email or providing any information as an attachment.
 - Therapeutic Specialists should respond to an email inquiry for more information on Sunovion products by requesting to meet the customer in person.
 - In rare circumstances, Sunovion Legal, or PMRC may approve emailing of product information to customers for specific, approved situations (e.g. important safety information).
 - Become a master and fully understand the details of appropriate email and texting. Never act without knowing. When in doubt, ask your manager.

GIFTS AND ITEMS OF VALUE

Tickets to an Event

Background

Susan, a Sunovion Therapeutic Specialist, has been in her current territory for many years with a variety of companies. She has built many strong relationships with her HCP customers.

One of her long term customers was one of the top prescribers of her products. At the end of a recent sales call with this customer, there was a brief discussion about a new show on Broadway. The HCP mentioned that she heard great reviews and Susan agreed it was supposed to be good. The HCP then asked Susan if she might be interested in going together, stating that she and her husband had a set of tickets but he was unable to go. She asked Susan if she wanted to take her husband's extra ticket and go with her.

Susan knew that the Sunovion policy on gifts did not permit giving anything of value to customers other than approved educational items. But she wasn't sure about receiving anything from a customer, especially one who she had known for so many years and considered a friend. Susan decided to say yes and accepted the ticket, but informed her manager that she would be going to the event.

GIFTS AND ITEMS OF VALUE Tickets to an Event

Question

- Did Susan make the right choice?
- Should she have accepted the ticket?
- Was informing her manager sufficient?



GIFTS AND ITEMS OF VALUE Tickets to an Event

Acceptable Response ✓

Thank you for the offer for the tickets, but I will have to decline. Because we have a working relationship, I do not want to give the appearance of a potential conflict of interest. Therefore, I will not be able to partake in these types of events with you in the future.

Unacceptable Response ✗

Here is an example of an unacceptable response.

I would love to join you. Since the tickets are free, I believe it meets our policies and compliance guidelines. Can I pick you up the night of the show around 6 p.m.?

GIFTS AND ITEMS OF VALUE

Tickets to an Event

Key Learning Points



- Susan knew that offering a physician or customer anything of value was not permitted. However, she was unsure of the conflict of interest policies and made a wrong decision to accept the ticket.
- To avoid the appearance of undue influence of customer treatment decisions or the perceptions of an improper relationship, accepting anything of value from customers is against Sunovion conflict of interest policies.

GIFTS AND ITEMS OF VALUE

Tickets to an Event

Putting Policy Into Practice

GIFTS AND ITEMS OF VALUE

- Don't offer HCPs or customers any form of gifts or items of value, unless they are approved educational items intended for distribution to HCPs.
- Become a master and fully understand the details regarding Sunovion policies on gifts and items of value. Never act without knowing. When in doubt, ask your manager.

CONFLICTS OF INTEREST

- Don't accept any gifts or items of value from HCPs or customers.
- If you are planning a non-Sunovion social event with an HCP or customer, or having regular, social interactions with an HCP or customer, you must disclose this to Sunovion's Compliance & Ethics Department.
- Whether social interactions are planned or unplanned, Sunovion business interests should not be discussed with HCPs or customers.
- Become a master and fully understand the details regarding conflict of interest policies. Never act without knowing. When in doubt, ask your manager.



SPEAKER PROGRAM

Lunchtime Program in a Hospital Setting

Background

Jackie, a Sunovion Therapeutic Specialist, set up a lunchtime speaker program at a local hospital. She had an approved speaker, Dr. Johnson, lined up and 10 HCPs scheduled to attend.

Dr. Johnson arrived and after surveying the small conference room for the program and lack of a screen for showing the slides, she suggested to Jackie that they turn the meeting into a roundtable discussion. Jackie politely disagreed with this suggestion because round table discussions are not permitted.

Dr. Johnson then suggested that she use her laptop for the presentation by placing it on the conference room table. Instead of cancelling the program, Jackie thought this would be okay.

Dr. Johnson began by showing a few slides on clinical efficacy but stopped before getting to the fair balance slides. Dr. Johnson then proceeded to answer questions on a variety of topics including several off-label questions. Dr. Johnson discussed the warnings and side effects of the product without showing any additional slides and concluded that this product was effective and generally safe. Jackie was not happy with the events of the program.

SPEAKER PROGRAM

Lunchtime Program in a Hospital Setting

Question

- What should Jackie say to Dr. Johnson and what should she do?
- Which speaker program guidelines were met and which were not?



SPEAKER PROGRAM

Lunchtime Program in a
Hospital Setting

Acceptable Response ✓

Dr. Johnson, as you are aware, Sunovion requires every speaker to show all slides, particularly those slides that offer fair balance for the presentation, and to discuss only approved indications. In the future, I would ask you to present the entire slide deck and to not discuss off-label indications or answer off-label questions with the general audience. I will do my part to make sure we have a venue that is large enough and has a screen for you to make a full slide presentation.

Unacceptable Response ✗

Here is an example of an unacceptable response.

Thank you for making a quick and impactful presentation of the data. I believe everyone appreciated your willingness to be flexible with the program given the room size, and for mentioning the warnings and side effects.

SPEAKER PROGRAM

Lunchtime Program in a Hospital Setting

Key Learning Points




- Given the circumstances, it was appropriate for Jackie to agree to proceed with the program using Dr. Johnson's laptop screen instead of cancelling the program. She could not have foreseen that Dr. Johnson would turn the program into a round table discussion.
- However, Jackie did not handle the situation effectively and could have been more prepared to prevent and handle these issues. Jackie should have:
 - Before the program, confirmed the room size and the availability of a screen and reinforced with Dr. Johnson the Sunovion speaker requirements, including the need to present all slides and to not discuss off-label questions with the general audience.
 - During the presentation, when off-label indication questions were asked, reinforced the approved indications and mentioned that no off-label discussions could take place.
 - After the discussion, reminded Dr. Johnson not to discuss off-label questions with the general audience.
- After the event, Jackie should have clearly documented what happened on the Sunovion speaker program checklist. Given that there were a number of issues with this program, Jackie should have also contacted her manager.

SPEAKER PROGRAM

Lunchtime Program in a
Hospital Setting

Putting Policy Into Practice

SPEAKER PROGRAM POLICIES

- 
- Before the start of every speaker program, ensure the venue is appropriate. Confirm that the speakers have the approved slides and remind them of the speaker requirements, including not answering unsolicited off-label questions in a group setting.
 - Discretely address any speaker infractions on-site directly with the speaker after the presentation.
 - Accurately document and report speaker infractions to your RBM via email within 24 hours.
 - Become a master and fully understand the details regarding speaker programs. Never act without knowing. When in doubt, ask your manager.

SPEAKER PROGRAM

Responding to Unsolicited
Off-label Questions

Background

Jose, a Sunovion Therapeutic Specialist, was looking forward to the speaker program he set up. Dr. Lexus, a well known local opinion leader, would be speaking. Dr. Lexus was well respected for his experience and had a reputation for being an effective presenter who enjoyed discussions with those in the audience.

Dr. Lexus arrived just in time for the start of the program. Jose greeted him, got him set up at the podium and started the program. The program was going well when midway through the presentation an attendee asked Dr. Lexus an off-label question. Dr. Lexus mentioned that he would answer all questions at the end of his talk. Dr. Lexus continued to present all of the slides and at the end of the presentation, spent 20 minutes answering questions for the general audience. He gave his personal opinion about the off-label question, but did mention what the approved indication was. Jose was relieved that Dr. Lexus had clarified the approved indication. He thanked the Dr. Lexus for his presentation and closed out the program.

SPEAKER PROGRAM

Responding to Unsolicited
Off-label Questions

Question

- Did Dr. Lexus handle the off-label question appropriately?
- Did Jose handle the situation appropriately?
- What should Jose say to Dr. Lexus?



SPEAKER PROGRAM

Responding to Unsolicited
Off-label Questions

Acceptable Response ✓

Thank you Dr. Lexus for an informative and engaging presentation. Regarding the off-label question, you appropriately clarified the approved indication. However, I want to remind you that answering off-label questions in front of the entire audience is against our speaker policies. Any unsolicited off-label questions related to our approved indication may only be answered one-on-one with the person who asked the question at the end of the program.

Unacceptable Response ✗

Here is an example of an unacceptable response.

Dr. Lexus, I wanted to thank you for a terrific speaker program tonight. The audience had many questions for you and I think they were pleased that you answered all of them. I really appreciated that you mentioned the product's approved indication.

SPEAKER PROGRAM

Responding to Unsolicited
Off-label Questions

Key Learning Points




- Jose only partially understood the speaker requirements. He understood that speakers should always clarify the approved indications when off-label questions are asked. However, he did not understand that speakers cannot address off-label questions in front of the audience.
- Even though Dr. Lexus was late arriving, Jose could have been more prepared to prevent and handle these issues. Jose should have:
 - Before the program, quickly reminded Dr. Lexus about the Sunovion speaker requirements, including the need to present all slides and to not discuss off-label questions with the general audience.
 - During the discussion, reinforced the approved indications and mentioned that no off-label discussions could take place.
 - After the discussion, reminded Dr. Lexus not to discuss off-label questions with the general audience.
- After the event, Jose should clearly document what happened on the Sunovion speaker program checklist.

SPEAKER PROGRAM

Responding to Unsolicited
Off-label Questions

Putting Policy Into Practice

- 
- Before the start of every speaker program, confirm that the speakers have the approved slides and remind them on the speaker requirements, including presenting all slides and not answering unsolicited off-label questions in a group setting.
 - Discreetly address any speaker infractions on-site directly with the speaker after the presentation.
 - Accurately document and report speaker infractions to your RBM via email within 24 hours.
 - Become a master and fully understand the details regarding speaker programs. Never act without knowing. When in doubt, ask your manager.



MODEST MEALS

Hospital Lunch and Learn

Background

A local teaching hospital has created a series of internal learning days for the hospital staff. The learning day activities include different companies having an opportunity to present their products to the department HCPs over lunch in the hospital conference room.

The hospital administrator asked Carolyn, the Sunovion Therapeutic Specialist, if Sunovion would be willing to participate in the upcoming learning day program. Participation would include a 15 minute presentation on Sunovion products, followed by 10 minutes of Q&A. There would be no charge or fee to participate, but the hospital administrator indicated companies would need to bring enough lunch to cover the entire department staff, approximately 25 people.

Carolyn thought this was a great opportunity to meet and present to the entire hospital team. However, she knew the conference room was small and wasn't sure about the request for meals. The Hospital Administrator needed a quick response or she was going to give the time slot and opportunity to another company. Carolyn decided to consult the Sunovion policies and speak with her manager before making a commitment.

MODEST MEALS

Hospital Lunch and Learn

Question

- How should Carolyn respond to the Hospital Administrator?
- Should Sunovion get involved in this type of activity and if so, is the location appropriate?
- What about the attendees and meals?



MODEST MEALS

Hospital Lunch and Learn

Acceptable Response ✓

Thank you for the opportunity to provide a presentation on our products at your upcoming learning day program. Given that this program is being offered to all companies, we would welcome the opportunity to participate. However, we have certain requirements regarding food and attendees:

- We can only present to those who might be involved in the use of our products.
- We can only provide a modest meal such as sandwiches and snacks with a limit of \$25 per HCP.
- We can only order enough food for those expected to attend, so we would need an estimated head-count before the program.
- Those who attend and receive a meal need to be part of the educational discussion; we are not permitted to provide just food. Attendees will need to stay for the duration of the presentation.
- Lastly, those who receive a meal will need to sign our attendee sheet which I can hand out at the start of the presentation. If this is acceptable, I will be able to gladly accept your invitation.

Unacceptable Response ✗

Here is an example of an unacceptable response.

Thank you for the opportunity to provide the meal and brief presentation on our products. As long as the attendees sign my program attendance sheet, we're good to go. I'll bring enough sandwiches for 30 people, would that be sufficient?

MODEST MEALS

Hospital Lunch and Learn

Key Learning Points




- Carolyn acted appropriately by first consulting the Sunovion meal policies and discussing the situation with her manager before making a commitment. A program with a large number of attendees with a meal could have compliance implications. For example:
 - There was the potential for 'dining and dashing', e.g. HCPs having a sandwich and are not participating in the educational discussion.
 - If the program had been offered solely to Sunovion and not other manufacturers, this could be an inappropriate benefit to Sunovion pursuant to kick-back regulations.
- In responding to the Hospital Administrator, Carolyn should be clear about the Sunovion requirements for meals and attendees. If the Sunovion meal and attendee requirements could not be met, Carolyn would need to decline the opportunity, or work with the Hospital Administrator to change the arrangement so that the Sunovion requirements could be met.

MODEST MEALS

Hospital Lunch and Learn

Putting Policy Into Practice

 LUNCH AND LEARN AND MEAL POLICIES

- 
- A hospital or clinic learning day program over lunch with HCPs and customers would be considered a lunch and learn program. Therefore, the same policies and procedures apply whether it is held in a physician's office or hospital conference room.
 - The attendees must be appropriate for that program.
 - The attendees must sign the attendance sheet.
 - The meal must be provided in the institution or physician's office.
 - The meal must be consumed during a medically relevant discussion.
 - The meal must meet the criteria of modest, occasional and abide by Sunovion meal expense limits of \$25 per HCP.
 - Meals with customers must abide by State Law requirements, as appropriate.
 - Record first and last names and all other required information of appropriate attendees.
 - Become a master and fully understand the details regarding lunch and learns and meal policies. Never act without knowing. When in doubt, ask your manager.

MODEST MEALS

Office Lunch and Learn

Background

Wendy, a Sunovion Therapeutic Specialist, visits a key clinic once a quarter and provides lunch for the promotional discussion. Typically, Wendy contacts the office to discuss the expected number of attendees and allows the office to place the order from a restaurant of their choice. Wendy always provides guidance on the Sunovion modest meal policies of \$25 per HCP. Wendy then picks up and pays for the order and brings it to the office.

A month before her quarterly lunch discussion, Wendy spoke to the office manager who said eight HCPs from the clinic were expected to attend. On the morning of the program, Wendy picked up the sandwiches and discovered the order was for twelve people. She paid for the order assuming that the number of expected attendees had changed.

When she arrived at the clinic, Wendy learned that several HCPs cancelled at the last minute and only four HCPs were attending. The office manager asked Wendy if she could leave the extra sandwiches for those that were missing the discussion. Wendy was not comfortable doing this but didn't want the sandwiches to go to waste. She decided to ask the office manager if she could see the missing HCPs later that day and the office manager agreed.

Later that afternoon, Wendy returned to the clinic and had sales calls with three other HCPs who were supposed to be at the lunch discussion. On her meal attendee report, she included the seven HCPs she spoke to that day. Her expenses included twelve sandwiches which resulted in her exceeding the per-person meal cost limits. Wendy notified her manager.

MODEST MEALS

Office Lunch and Learn

Question

- Did Wendy handle the situation appropriately?
- What could Wendy have said to the office manager?
- What could she have done to prevent this situation from happening?



MODEST MEALS

Office Lunch and Learn

Acceptable Response ✓

I won't be able to leave the extra sandwiches. Our policy requires that we only provide meals in conjunction with a business discussion. Also, going forward I will need to place the orders for our lunch discussions as that is part of my responsibilities. For future programs, I will call you a couple days before to confirm the number of expected attendees. Does that work for you?

Unacceptable Response ✗

Here is an example of an unacceptable response.

I will leave the extra sandwiches with you. There are more than we needed, due to the cancellations, and I don't want them to go to waste. I am sure someone in the office will be able to enjoy them.

MODEST MEALS

Office Lunch and Learn

Key Learning Points



- Wendy acted appropriately by informing her manager of the situation, including her exceeding the meal limits.
- However, she did not act appropriately to prevent these issues from taking place.
 - She should not have let the office place the order.
 - She did not confirm the number of expected attendees the day before.
 - She should not have left the plate of extra sandwiches, which significantly exceed those who ate lunch during the discussion.
 - She assumed that those she would speak to later in the day would have a sandwich without knowing who had provided them.
- To prevent this situation, Wendy should have:
 - Placed the order herself.
 - Confirmed the number of attendees the day before.

MODEST MEALS

Office Lunch and Learn

Putting Policy Into Practice

 MODEST MEAL POLICIES

- Confirm the appropriate number of people expected to attend the discussion and order modest amounts.
- Ensure meal attendees are appropriate for that business discussion and accurately document all appropriate meal attendees.
- If, after good planning as to the expected number of attendees, there is left-over food that is not excessive, it is appropriate to leave the food behind.
- If your meal exceeds the \$25 per HCP or there are any other issues with meals and attendees, inform your RBM about the exception. Never falsify documentation to cover a mistake.
- Do not use personal funds to pay for meal overages, split charges with Sunovion colleagues or others, or divide the bill into multiple receipts.
- Become a master and fully understand the details regarding lunch and learns and meal policies. Never act without knowing. When in doubt, ask your manager.



MODEST MEALS

Coffee

Background

Fred, a Sunovion Therapeutic Specialist, loved to drink coffee. He liked to share his passion for coffee by bringing cappuccinos with him to share with his HCP customers during product promotions. He felt that this was an effective way to have a product discussion while building his relationships with his customers. On occasion, he would also bring a cappuccino for the office receptionist and share with her his expertise on a great cup of coffee. Sometimes, if the HCP was not in the office Fred would leave the cappuccino with the receptionist.

Fred felt that a cup of coffee was a small gesture and usually only cost \$3-4 dollars. He would often expense the coffees and document which HCP he had a coffee with. Sometimes he would just pay it out of his own pocket.

Fred felt that his product presentations over a cup of cappuccino were so successful that he decided to do this on almost every sales call. He was quickly becoming a regular fixture and was known to his customers as the cappuccino king.

Fred was invited to the office holiday brunch and asked to bring coffee for the entire staff. He was unsure about what to do. He decided to attend and pay for the coffee out of his own pocket.

MODEST MEALS Coffee

Question

- Can Fred provide coffee to the office as long as he pays for it himself?
- Can Fred provide a coffee during a promotional discussion with an HCP?
- Is Fred's behavior of providing a coffee on most of his sales calls and his expensing of these coffees appropriate?



MODEST MEALS Coffee

Acceptable Response ✓

I would love to but unfortunately, I cannot. My company's policy does not allow me to pay for even a minimal expense out of pocket and if I expense it, it has to be a part of a product discussion with a HCP. I am quite sure that we will not be talking business at this event.

Unacceptable Response ✗

Here is an example of an unacceptable response.

As long as I don't expense it and it is a social gathering rather than a business meeting I am sure it will be okay. After all, it's only a cup of coffee and the upside potential far outweighs any risk.

MODEST MEALS

Coffee


Key Learning Points



- Fred can provide a coffee during a business discussion with an appropriate HCP.
- A coffee, although modest in expense, is considered a modest meal. Fred did not comply with the Sunovion modest meal policies in a number of areas:
 - Fred should not be providing coffee on every sales call. Modest meals, including coffees, should only be provided occasionally. Good judgment should be used to ensure that the frequency of modest meals and coffee is not seen as a potential enticement to access customers, or an enticement to prescribe.
 - Fred should not provide coffee to the office receptionist. Modest meals should only be provided to HCPs.
 - Fred should not be paying for coffee out of his own pocket. Any modest meal expenses need to be properly documented and expensed.
 - Fred should not buy a coffee without confirming that he will be having a business discussion with an appropriate HCP over a modest meal (the coffee).

MODEST MEALS Coffee

Putting Policy Into Practice MODEST MEAL POLICIES

- 
- Confirm the appropriate number of people expected to attend the discussion and order modest amounts.
 - Ensure meal attendees are appropriate for that business discussion and accurately document all legitimate meal attendees.
 - Do not use personal funds to pay for meal overages, split charges with Sunovion colleagues or others, or divide the bill into multiple receipts.
 - Never falsify documentation to cover a mistake.
 - Become a master and fully understand the details of modest meal policies. Never act without knowing. When in doubt, ask your manager.