THE H O T

Welcome to the Fall 2016 issue of The Hoot, Purdue's Ethics & Compliance newsletter for Sales Force colleagues. We hope that you find this newsletter informative and look forward to your feedback for future issues.

By Tracey Cunningham, Michael Grandison, Deisi Rosas, & Angela Stewart

REMINDERS

HCP Expenses – Refreshment Category

➤ Beginning with expenses that take place after July 1, 2016, HCP expenses that are $5 or under will be considered a "Refreshment" and will not be counted in the HCP meal counts in Phoenix, or in the HCP Meal spend budget report. Such expenses are still recorded and reported for Sunshine Act requirements.

➤ A new report has been added to Phoenix that provides a list of all HCPs that have had "refreshments" and includes the YTD total for those refreshments. Refer to Phoenix bulletin #187 for additional information.

➤ Phoenix Updates – Customer search has been updated and can now be scrolled independent of the rest of Phoenix. Selecting "Go" on the iPad keyboard will now initiate the customer search. See Phoenix bulletin #184 for details.

➤ Be mindful of the end of the year moratorium on HCP meals. No meals are to be provided to HCPs after **December 14, 2016**.

COMPLIANCE SCENARIOS

Dear Angela:

I can't attribute an HCP Expense in Phoenix. My expense date is incorrect. How can I fix this?

"Curious Colleen"

Dear Colleen,

You would request correction for the HCP expense entry in Phoenix.

Request Exemption/Correction

Additional HCP Expense guidance can be located in bulletin #248 on the Phoenix desktop library.

Angela

Dear Mike:

Is the Ethics & Compliance Hotline truly anonymous?

"Doubtful Brian"

Dear Brian,

The Ethics & Compliance Hotline (the "Hotline") is operated by a third-party vendor, and is available 24 hours a day, 365 days a year. When you call you may choose to remain anonymous, or not. Under Company policy, you cannot be retaliated against for asking questions or raising good faith concerns about possible improper conduct.

Mike

Have a story to share? It can be a success or challenge you might have faced – what was the resolution?

Send it to compliance@pharma.com

COMPLIANCE TIPS...

- *Prior Authorizations*
    - Sales Force Personnel are PROHIBITED from engaging in processing prior authorizations, including but not limited to:
        - Promoting guarantee of favorable access and coverage outcomes
        - Calling the Hysingla ER Coverage and Access Support Program or CoverMyMeds directly on behalf of offices or patients
        - Reviewing and/or pushing along paperwork and processing steps associated with patients
        - Instructing an HCP or staff member on how to fill out a form in order to guarantee coverage
        - Calling an insurance company on behalf of an office or specific patient
        - Filling out a form
        - Entering data into CoverMyMeds or submitting data directly to the Hub on behalf of the HCP
        - Receiving personally identifiable healthcare information. This is a violation of HIPAA.
    - The following is PERMITTED:
        - Utilize approved materials to discuss CoverMyMeds or the Hysingla ER Coverage and Access Support Program
        - Provide an overview of plan requirements consistent with approved messaging/materials
        - Ask general questions that may help a customer with the status of a prior authorization

- *Adverse Event and Product Complaint Reporting*
    - Purdue has obligations to monitor Adverse Events and Product Complaints that are associated with its products. For more information, you can access Purdue's Healthcare Law Compliance Policies under the Policies and Standards homepage.
        - An **Adverse Event** is any unwanted or unintended experience in a person that is associated with the use of a drug, whether or not that experience is caused by that drug. This includes any known side effects.
        - A **Product Complaint** is any untoward occurrence with the physical characteristics of a product or with the product's packaging, labeling, immediate container, closure, or contents.
    - If you learn of an Adverse Event or Product Complaint, report the incident <u>as soon as possible</u>, but no later than 48 hours after learning of it via one of the following mechanisms:
        - Phone: (888) 726-7535, prompt 2 (to report an Adverse Event) or prompt 3 (to report a Product Complaint)
        - Fax: (203) 588-6395
        - Electronic Reporting:
            - 1) Send an email to report an adverse or unwanted experience associated with the use of a Purdue product to the "Drug Safety and Pharmacovigilance" or "AE Report" address in Outlook (or email to: drugsafetyandpharmacovigilance@pharma.com).
            - 2) Send an email to report a product complaint to the "Product Complaints" address in Outlook (or email to: productcomplaints@pharma.com).
            - 3) Individuals with access to the Phoenix system should use Phoenix.

- *Two points of clarification for Military Treatment Facility (MTF) Engagement*
    - Meals in MTFs:
        - Be mindful that some MTFs will not expect or allow food/beverages or meals from pharmaceutical companies. Before providing a meal, please clear it with your manager. Should a meal be permitted to take place, the expectation is that it should be tracked manually from all sources so not to exceed the limits of $20 per person per event, with a maximum spend of $50 per recipient per year from all Purdue sources. Once a tracking feature is enabled in Phoenix, further direction will be provided.
    - Access to MTFs:
        - A formal process is being finalized. Requests can be sent to institutionalpolicy@pharma.com. Include as much information as possible regarding access requirements, including links to the MTFs' sites and/or documentation the site may have provided (in PDF format). A two (2) week turnaround time should be expected before access may be obtained.   You will receive approval, in writing, once the request has been reviewed. Once the formal Meals and Access processes are finalized, another formal memo will be issued.
    - Reminder:
        - Federal government employees are permitted to attend speaker programs but are not permitted to partake in the meal provided.