



G&I HEALTH
Connecting Your Compliance Dots

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Hub Services

- A sales representative collaborates with a field reimbursement manager
- FRM regularly receives weekly reports containing de-identified prescription data.
- The sales representative identifies an office with several patients who haven't been refilling their prescriptions.
- Concerned about this trend, rep utilizes the de-identified information to help the office identify patients and ultimately order their refills
- The office staff cant figure out the patients with the de-identified data
- Rep requests and receives more data on these patients from the FRM or the Hub and gives the patient information to the office

Aggregate Spend

- Aggregate Spend team identifies several problems in the data
- The field is not capturing accurate information on the sign in sheets
- Aggregate Spend team requests discontinuing the use of sign in sheets for speaker program meals and in-office meals

PDMA

The field team wants to provide samples at clinics within a chain drugstore, such as CVS Minute Clinic.

Regulatory Awareness

Numerous recently enacted and pending state and local regulations have the potential to greatly affect your business. These include alterations to state licensing prerequisites, the introduction of state or local drug take-back initiatives, employee licensing and registration, lobbyist registration, expenditure reporting, sample distribution, price disclosures, call details, and more.

CT Requirements

Connecticut (CT) has recently implemented a new regulation that:

- Mandates the registration of sales representatives.
- Requires a written list price disclosure when conveying information to prescribers or pharmacists.
- Necessitates the inclusion of any available data on variations in drug efficacy among different racial and ethnic groups for legend drugs.

CMS Audits

- In one of the CMS pilot audits, one company was unable to provide evidence of payments made to Healthcare Providers (HCPs).
- The manufacturer had enlisted the services of a vendor to process these payments, but the vendor no longer offers this service to the company.

Exhibits

It is a common practice for companies to receive invitations to participate as exhibitors at industry events. In most cases, companies will request:

- A formal letter of invitation,
- A copy of the event agenda to ensure that attendance is appropriate,
- The allocated time for customers to engage with exhibitors,
- W-9

Written Communication

Maintaining written documentation presents a significant area of risk for any organization. Instances of improper documentation can manifest in various communication formats, including emails, text messages, internal chats (e.g., Teams), account planning documents, and sales coaching notes, among others.

Medical/Commercial Interactions

Medical affairs and the commercial team intend to engage in shared interactions aimed at bolstering pipeline development and pre-launch initiatives.

Field Monitoring

How can we enhance field monitoring to transform it into an opportunity for identifying and addressing pain points within the organization?

Virtual Meals

- A sales managers requested approval for a meal to be delivered to an office during lunchtime
- The sales manager explained that this meal would be consumed during a zoom call with the HCP
- This is because this office only permits virtual interactions with the HCP

Risk Sharing

- A physician procures a product intended for patient administration in an outpatient setting.
- Following the diagnosis, an in-office procedure, involving the injection of the product, is conducted.
- Subsequently, a benefits investigation is carried out after the product has been administered, revealing that the patient's insurance provider does not approve reimbursement for the product.
- The company wants to indemnify the physician and provide a reimbursement for the product

Thank you