



Huron
CONSULTING GROUP

**Aggregate Spend
and
State Reporting**

November 12, 2009

**Do You Know
Where Your
Third Parties
Are?**

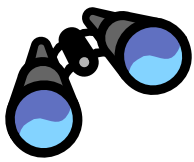
**THE TENTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS
AND BEST PRACTICES FORUM: PREPARING FOR THE NEXT WAVE OF CHANGE**

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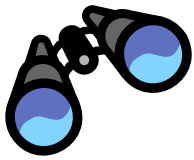
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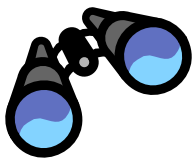
Agenda

- ◆ Who Are Your Third Party Vendors?
- ◆ Importance of Identifying TPVs and Their Activities/Spend
- ◆ TPV Identification
- ◆ What Should TPVs Report Back to Your Company?
- ◆ Potential Ways TPVs Should Report Back to Your Company
- ◆ To-Do List





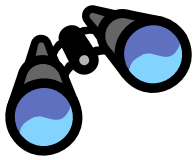
Who are your TPVs?



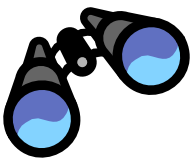
Who are your TPVs?

- ◆ ***Third party vendors (“TPVs”) include any external vendors which conduct activities on behalf of or provide services for a company.***
- ◆ Pharmaceutical companies currently engage vendors to assist in coordinating a variety of activities, such as:
 - Speaker programs
 - Advisory boards
 - Market research
 - E-detailing
 - Teleconferences
 - Investigator meetings
 - Steering committee meetings
 - Educational item fulfillment
 - Travel arrangements
 - Clinical trial payments
 - IIS
- ◆ Many of these activities involve spend being provided to an HCP (including meals, travel, educational items, payments/honoraria and reimbursements).





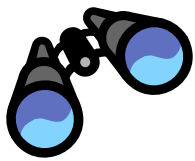
Importance of Identifying TPVs and Their Activity/Spend



Importance of Identifying TPVs and Their Activity/Spend

- ◆ TPVs include any external vendors which conduct activities on behalf of or provide services for a company.
- ◆ TPVs are acting as agents of a Company.
- ◆ Their activity is ultimately the activity of the Company.
- ◆ The state laws and pending federal laws cover spend to Healthcare Providers and Healthcare Organizations which are often paid by TPVs.





Importance of Identifying TPVs and Their Activity/Spend

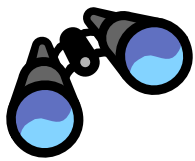
State Laws

◆ HCP/HCO Spend Disclosure

- Many of the laws include disclosure of spend and payments to HCPs/HCOs (DC, MA, ME, MN, WV, & VT).
- TPVs often pay HCPs on behalf of companies and provide meals, gifts, travel, and other in kind expenses.
- This TPV information will have to be aggregated with other company data for state spend disclosure.

◆ HCP/HCO Spend Limitations

- Two states have limitations on gift and meal amounts spent on HCPs in their states
 - CA Comprehensive Compliance & Reporting Law requires that companies establish their own limits for meals and gifts to HCPs
 - MN has a gift limitation of \$50 per HCP per year
- TPVs often pay HCPs on behalf of companies and provide meals, gifts and in kind expenses.
- This information will have to be aggregated on an ongoing basis with other company data to determine if a cap has been reached.
- Applies across the entire business (commercial, medical, research and development)



Importance of Identifying TPVs and Their Activity/Spend

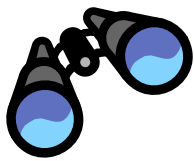
State Laws

◆ Prohibitions of Activities involving HCPs/HCOs

- Several of the states also have certain prohibitions of activities involving HCPs (MN, VT, & MA)
- TPVs are responsible for abiding by the same prohibitions as the company.
- Companies will need to communicate their expectations and interpretations of these laws regarding specific activities and take measures to ensure that these prohibitions are being maintained.
 - Important to build these requirements into the vendor agreement.

◆ Monitoring & Auditing State Laws (NV & MA)

- Some of the state laws (NV & MA) require certification that a manufacturer has conducted audits as part of its compliance program.
- Monitoring/auditing should include activities of TPVs.
 - TPVs should be informed of this requirement and will have to potentially provide data and other documentation for the audit.
 - Important to build these requirements into the vendor agreement.



Importance of Identifying TPVs and Their Activity/Spend

State Laws

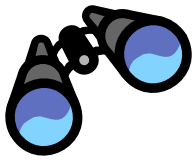
◆ Disclosure of Direct Consumer Advertising Costs

- Some of the state laws require that companies report certain advertising costs (DC, MA, & WV)
- Often companies hire TPVs to perform, create, distribute such advertising materials.
- Companies will need to communicate their expectations on certain costs they need to collect and how these need to be calculated.
 - Vendors should be becoming more sensitized to these issues.

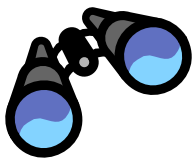
◆ Physician Payment Sunshine Act (pending federal law)

- Requires reporting of payments on a national level
- May not pre-empt the state laws
- Currently includes areas that are not covered by state laws (e.g. certain clinical spend, CRO activities, etc.).



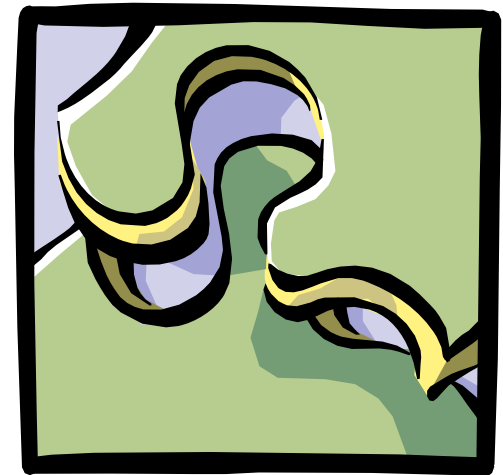


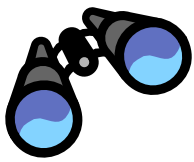
TPV Identification



TPV Identification

- ◆ An initial identification of TPVs will need to be conducted, and the list of TPVs will need to be maintained/updated on an ongoing basis.
- ◆ Companies should consider creating a consolidated list of all TPVs used throughout the company.
- ◆ Once included, consider verifying for accuracy

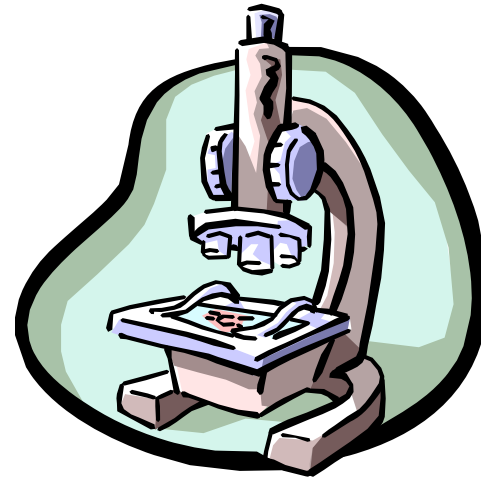


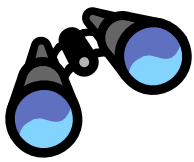


TPV Identification

Where are My TPVs Located?

- ◆ TPVs can be under contract throughout pharmaceutical companies.
- ◆ Some of the areas in which TPVs may be found include but are not limited to the following:
 - Clinical Operations (e.g., CROs)
 - R&D
 - Medical Affairs
 - Managed Markets
 - Sales
 - Marketing
 - Marketing Research
 - Training
 - Public Relations
 - Government Affairs
 - Regulatory Affairs
 - Medical Science Liaisons
 - Medical Communications





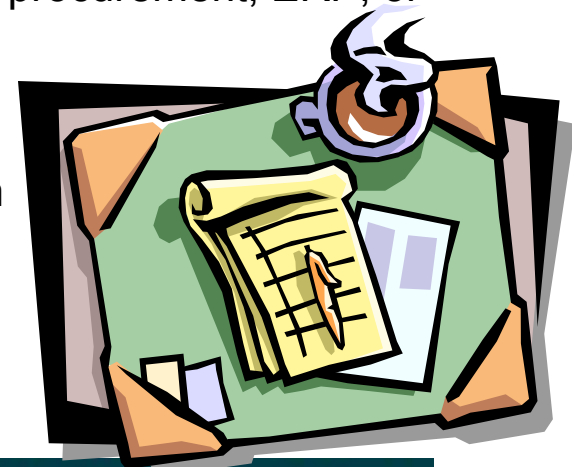
TPV Identification

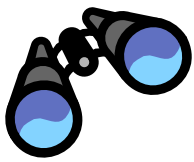
Initial Identification of TPVs

- ◆ To create an initial list, companies should consider:
 - Contacting all areas of the business, including all business units
 - Note: this may also include international areas
 - Using a validated process for identification of TPVs
 - Ask business units specific questions about exactly what types of vendors they use and what activities they perform
- ◆ Employee education on the importance of identification will be critical to a successful effort
- ◆ Companies may be able to find relevant information in procurement, ERP, or purchase order systems

Maintenance of the existing list of TPVs

- ◆ Often, this can be maintained in an automated fashion in an existing system
 - For example, an ERP system may be able to maintain this list automatically
- ◆ The TPV list can also be maintained manually



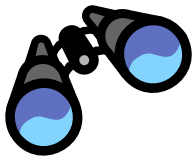


TPV Identification

Ongoing Identification of New/Updated TPVs

- ◆ It is important to ensure that as new TPVs are added or existing TPVs have new activities, that these TPVs are identified and tracked.
- ◆ Companies can specify an area or department which will be responsible for controlling the TPV list on an ongoing basis.
- ◆ It is important to have a process to ensure that as new vendors are added in a company, they are able to be efficiently identified and tracked.
- ◆ Some considerations include:
 - Creating compliance awareness within business units via employee education
 - Addressing Procurement Process
 - Reviewing and potentially changing the ERP or Procurement System
 - Getting access to people / documents / systems



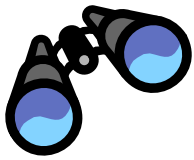


What Should TPVs Report Back to Your Company?

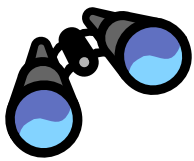


What Should TPVs Report Back to Your Company?

- ◆ A Company should determine a specific, predetermined list of the types of expenses that need to be reported to them, the level of detail of information, the method of reporting, the frequency of reporting, and for some, the format of the report.
- ◆ When determining this information, companies should consider what data they will need for Aggregate Spend (State Laws), Auditing & Monitoring Requirements, Company SOPs, and other Compliance rules that may apply.
 - Flexibility is critical given the unpredictability of new state laws and new federal laws.
- ◆ Companies can further ensure compliance with reporting requirements by instituting changes to the payment processes to ensure that this information must be received prior to payment of invoices.



Potential Ways TPVs Should Report Back to You



Potential Ways TPVs Should Report Back to You

Examples of Reporting Methods

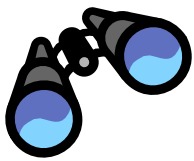
◆ **Companywide Vendor Portal**

- Some companies have built or purchased their own vendor portals that all vendors use to input information
- Vendors can provide information via a file feed or enter it directly into the portal

◆ **Documents Submitted to Company**

- Companies have created a standard spreadsheet/tracking mechanism which they distribute to all TPVs.
- Companies have also requested detailed invoices from TPVs.
- TPVs often then send these documents back to the specified individuals at the company.
 - Companies collect the information by various roles: Compliance, Finance, Business Units, etc.

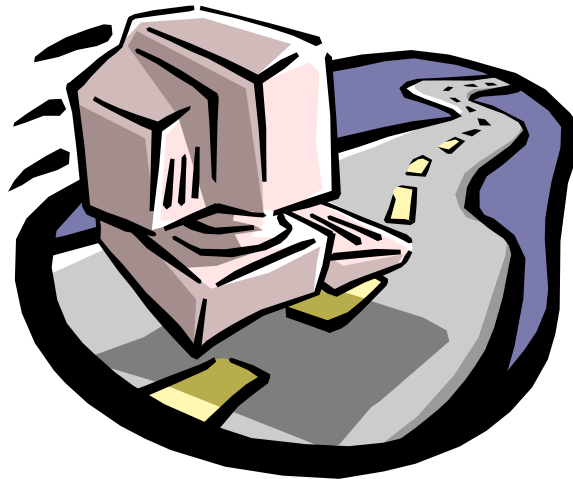


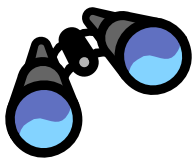


Potential Ways TPVs Should Report Back to You

Examples of Reporting Methods

- ◆ **Specific Vendor websites/portals**
 - Many TPVs have their own websites or portals where they track information.
 - Companies often have access to these (may be able to download reports)
 - These websites/portals may need to be updated to meet the reporting needs of the company.





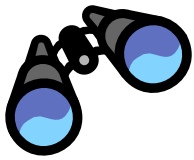
Potential Ways TPVs Should Report Back to You

How Can Technology help with TPV Reporting Capabilities?

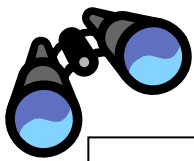
- ◆ Reporting Tools
 - Build/Purchase Company TPV Portal
 - Direct Entry
 - Download capabilities
 - Data validation, management, and exception processing
 - Update Existing Company Portals
 - Update Individual TPV run Portals/Websites

- ◆ Integrating into Aggregate Spend Tools
 - Purchase TPV Portal as part of Aggregate Spend Tool
 - Integrate Portal into Aggregate Spend Tool
 - Company TPV Portal
 - Individual TPV-run Portals





To-Do List

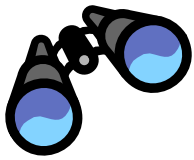


To-Do List

TASK

DATE COMPLETED

- | <u>TASK</u> | <u>DATE COMPLETED</u> |
|--|-----------------------|
| <input type="checkbox"/> Create/Review an easily updatable TPV list that is company-wide across all business units (Does your company have a complete list?) | |
| <input type="checkbox"/> Create/validate the process of updating the list of TPVs on an ongoing basis (How is this updated? Is it outdated?) | |
| <input type="checkbox"/> Verify that the TPVs are all reporting their spend in a consistent method (Do you have a process or mechanism for capturing and validating this spend regularly?) | |
| <input type="checkbox"/> Provide regular instruction and education to TPVs to ensure that all state required spend is being required and defined for reporting purposes
(Have you properly defined reporting requirements, a reporting schedule, and the level of detail of data needed?) | |
| <input type="checkbox"/> Ensure that monitoring and auditing of TPV reporting is being conducted and proper findings are addressed
(Are your processes being reviewed/is the data being reviewed?) | |
| <input type="checkbox"/> Include language in your TPV contracts to help ensure compliance with company requirements. | |



Questions?

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