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WHITE PAPER

Basking in the Sunshine – A guide towards complying with the Physician Payment Sunshine Act

The Pharmaceutical & BioTech industry is not alien to onerous and constantly changing government regulations. The imminent 'Sunshine Act' will test even the most prepared companies. With no preceding programs to serve as benchmarks, the Sunshine Act is expected to be complex and expensive to maintain for many companies. One of the key areas of focus is Compliance. With huge penalties for erroneous information, companies can no longer afford to take this lightly.

BACKGROUND:

The newly passed Physician Payment Sunshine Act (PPSA) requires companies to fully record any payments or benefits provided by pharmaceutical companies to Health Care Providers (HCP). Companies are expected to record all transactional data in 2012 with an annual report due on March 31, 2013 to the Secretary of Health and Human Services (HHS). This is expected to present substantial challenges due to the complexity of the requirements. Most companies currently use multiple disparate systems to manage this process including payments and benefits.

Typically, T&E expenses such as meals, travel and others are handled by the company's expense reporting process while bigger items such as consulting / speaking fees, research grants etc. are tackled by the company's CRM or Event Management system. In most companies, approximately 75% of all HCP transactions are recorded in the expense reporting system. These transactions typically account for 15-45% of the total HCP spend, thereby making them sizeable.

Thus, it behooves companies to fully understand the PPSA and abide by the exact requirements to avoid being penalized. Particularly important is being compliant to all requirements while also tackling additional administrative burden. Most companies must also review their existing reporting systems to ensure that the information is captured accurately. With constantly changing government regulations, companies must also be able to adapt quickly and maintain timeliness with submission of data.

In order to successfully navigate the requirements and prepare for compliance, co-ordination between various internal departments such as Finance, IT, Legal, Sales, and Travel department is required. Companies should employ internal groups and Subject Matter Experts (SME) to handle the PPSA. Some of the preliminary discussion points should include:

- What is the Sunshine Act?
- What are the company's legal requirements?
- Where do we start from a system point of view?
- How to manage all the HCP related data?
- What are the various business processes and procedures?
- What kind of systems will track aggregate to monitor HCP thresholds?

Some companies may attempt to meet the requirements with gradual, but comprehensive systemic and organizational change. Others, at their own peril, may assume that their current systems are adequate to handle the challenges.

But it is prudent to take a closer and honest look at the various options. Failure to produce a scalable, conformable and repeatable process will result in confusion and erroneous reporting leading to potential fines and negative publicity. During this introspective phase, companies should also pay attention to global legislation, the FCPA (Foreign Corrupt Practices Act) and requirement for compliance in the State of Residence. This white paper summarizes guiding steps with a general look at the 'What', 'How', 'When' and 'Where' of maintaining compliance with the Sunshine Act.

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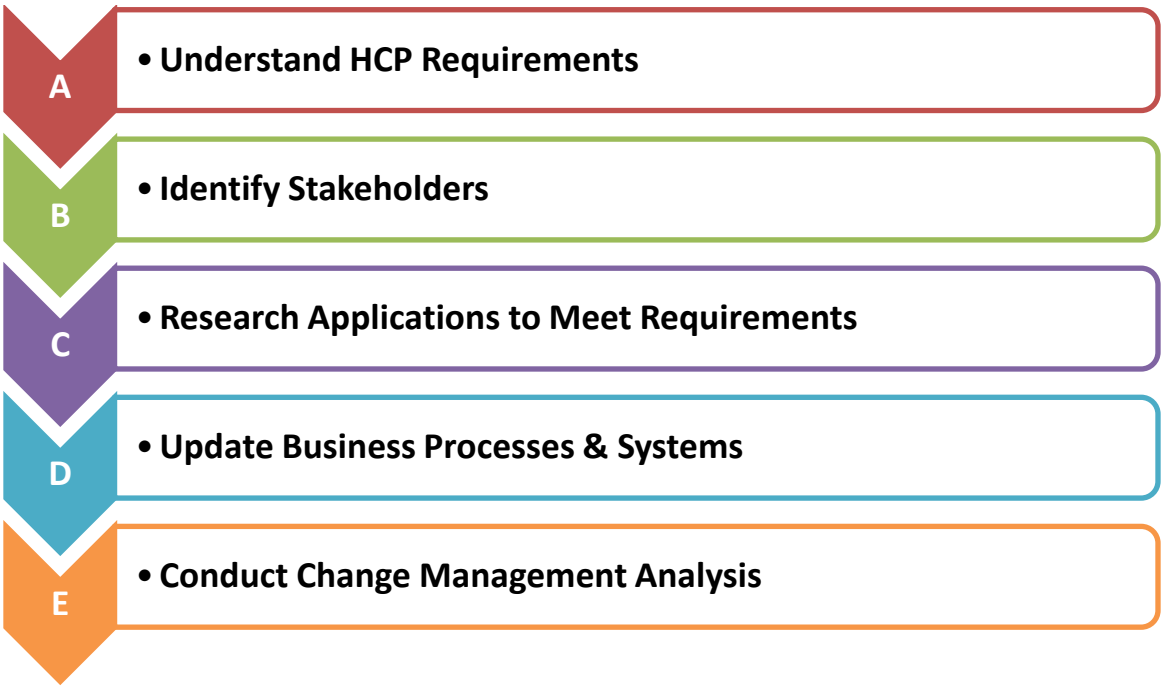
So what is the first step?

A famous maxim is - *'A job well begun is half done'* and this couldn't be more valid here. The best way to start this process is by looking at a five-step approach (see figure 1 below) to successfully execute business changes without unsettling the existing workflow. Companies that have existing reporting solutions will also benefit from reviewing their reporting strategy to ensure that all new laws are met effectively.

Figure 1 – Five step approach towards achieving compliance



A) **Understand HCP requirements** - The first step is to understand the new laws and how they differ from the company's current understanding of the requirements. At this stage, it would be prudent for companies to bring in their Legal, Audit & Compliance departments so that specific requirements are understood in detail.

B) **Assign stakeholders** – Once the requirements are understood, companies should kick-off the project by selecting stakeholders who will carry on the tasks. It is important to have a team of professionals with a combined background in project management, accounting, finance, audit & regulatory areas of expertise. Most importantly, executive support & buy-in is required to implement changes to the various systems and corporate processes.

C) **Research applications to meet requirements** – The next step is to research and identify applications that will help in the capturing and reporting of data. For this, business owners must know how they currently track & report spend, which systems are used, which systems need to be upgraded and what additional information is required.

D) **Update business processes and systems** – Once business owners determine new requirements, legal obligations and regulatory needs, the stakeholders proceed to obtain approvals and execute next steps towards aligning the business processes and systems. If the IT systems and corporate processes are to be modified extensively, the stakeholders must ensure that it is done with least impact to the user. In case there is sizeable impact, the stakeholders must organize and present some form of educational session or a training program to bring everyone up to speed on the new requirements and elaborate on the changes to expect.

E) **Conduct change management analysis** – Once all of this is done, companies must list and convey the importance of all the legal requirements to the employees. The company must also communicate the corporate responsibilities for each employee or team as well as set the expectations to meet regulatory compliance consistently. Due to the dynamic nature of this process and inherent challenges, strong collaboration is required through all stages to succeed.

Let us look at the 5 different steps in detail.

A) Understand HCP requirements

Basic regulations

On March 22, 2010, the Physician Payment Sunshine Act legislation was passed. The Act states that any device, drug or medical supply manufacturer operating in the US must report any payment or benefit provided to a physician or HCP. Payments under $10 are excluded, only if the total spent on that physician or HCP is less than $100 annually.

Companies must begin capturing and recording this data in 2012. The first report must be filed with the Health and Human Services (HHS) Secretary by March 31, 2013. Subsequent reports will be due at the end of March every year. Companies will need to act quickly to accommodate the procedural, planning, system and process changes required to meet this regulation.

All the submitted reports must be electronic, easily downloadable, and searchable. The following table (figure 2) offers a snapshot of all the information that is required in each report:

Figure 2 – Reporting parameters

Information required to report	1. Physician or HCP name 2. Business address 3. Physician specialty 4. National provider ID 5. Payment value 6. Form of payment 7. Payment date 8. Payment type (see below) 9. The name of the related drug or device or supply
Payment types	a. Gift b. Travel c. Food d. Honoraria e. Entertainment f. Research g. Profit distribution h. Charity contribution i. Education j. Consulting fees k. Speaking or speaker fees l. Royalties m. Dividends n. Stock options o. License fees

Penalties for non-compliance

The penalties for not complying with regulations are steep for companies, thus leaving little room for wrong interpretations. Companies will incur a penalty of $1,000 to $10,000 for each payment not reported. The upper limit that cannot be exceeded is $150,000 annually. Intentionally failing to report will result in a penalty of $10,000 to $100,000 for each payment and this is to not exceed $1,000,000 annually.

It is obvious that plenty is at stake here. Companies cannot be lax with their reporting and compliance structures. Adding to the rules imposed by the federal government, companies will also need to comply with additional rules set by states. Here are some state specific regulations:

Figure 3 – Additional reporting regulations per state

Data to capture	D.C.	Maine	Minnesota	Vermont	Massachusetts
Date	Payment date	Date		Date expense incurred	
Nature	Nature of payment	Nature	Specific reason for payment	Nature of expense	Payment ID
Purpose	Primary/secondary purpose	Purpose	Specific reason for payment	Purpose of expense	Payment ID
Value	Value	Value	Value of payment	Value/amount of expense	Amount of payment
Profession	Recipient type	Recipient credentials		Type of recipient	
Last name	Recipient last name	Recipient last name	Last name of practitioner	Last name	Recipient full name
First name	Recipient first name	Recipient first name	First name of practitioner	First name	
Middle	Recipient MI			MI	
Identifiers				State license number	Recipient ID
Professional designation	Recipient credentials		Professional designation		
Affiliation	Recipient affiliated facility	Facility			
Address			Street, city, state, zip		
Organization name	Non-individual recipient	Recipient detail		Name	Covered recipient full name
Organization type	Recipient type	Facility		Type of recipient	
Description of organization type	Other type			Only if 'Other'	
Product / areas	Product marketed			Product name	
Product type				Product type	
Trade secret	Trade secret				
Trade secret – more details	Trade secret explanation				

The Rules are constantly changing

The rules to comply with reporting requirements are constantly changing. The Center for Medicare & Medicaid Services (CMS) issues regular updates about reporting structures, deadlines and other information that is extremely pertinent for compliance. Therefore the legal departments within companies must frequently review applicable federal and state requirements and laws.

There may be additional specific requirements or codes mandated by the state. For example, a state's code might require to capture aggregate spend by doctor and not by organization. In that case, companies need to track spending by the doctor even if he/she is employed by multiple organizations and set limits accordingly.

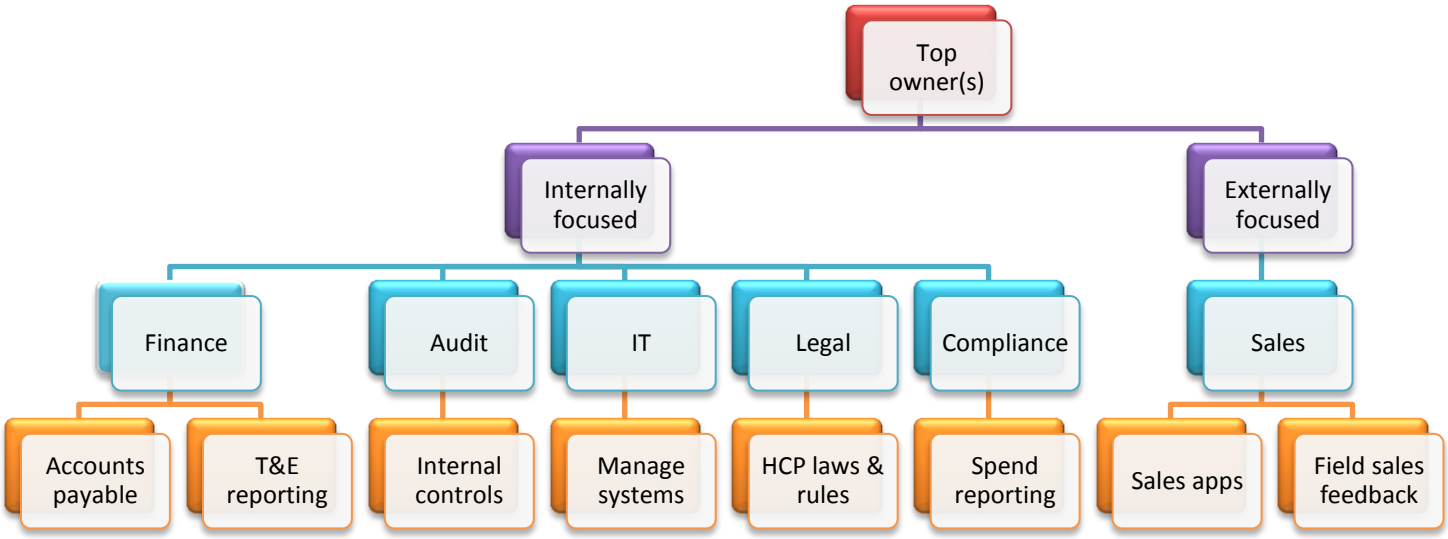
Due to the complex nature of this regulation, even if all the rules are concretized and understood, companies should not be complacent and schedule a regular review cycle with experts from IT, accounting, finance, audit & law to remain up-to-date with changes and new requirements. This will prevent unnecessary fines and penalties from being imposed due to negligence.

B) Identify Stakeholders

In general, payments and benefits offered to HCPs align directly with business objectives of the company. The reasons for providing such benefits range from presenting a new drug/device to lending educational assistance so that the medical industry can advance on the whole.

Since various business processes are involved, when a company looks at HCP related spend, it will find that these initiatives are managed and supported by the different operating groups and departments within the company. Each of these departments will have stakeholders who control the different aspects of this spend. Broadly, they can be broken down into external owners and internal owners. Here is a typical hierarchical structure in most companies:

Figure 4 – Hierarchy of internal & external stakeholders



Where do we start?

Due to the complex nature of the PPSA requirements, the company will need to involve internal experts from various departments as well as external vendors to make the project successful. This makes the task inherently complicated to manage and control.

The first step towards retaining control is to appoint a steering committee that will maintain oversight of the project as well as avoid roadblocks. Since time is a critical element here, the steering committee must be able to take decisive action quickly while identifying risks and goals. The steering committee must include individuals who will have a stake in the outcome of this project.

Next, the company must identify a team leader or owner who will be responsible for all the cross-functional coordination and communication between the various groups, external teams and vendors. Typically this individual is someone with a finance background and with experience and understanding of compliance and technology.

Finally, key members from the different departments identified in figure 4 should be assigned to the project to work under the direction of the team leader. These individuals will be responsible for performing due diligence within their area of expertise as it pertains to the needs of the company to meet PPSA requirements.

It might be beneficial for the company to include more than one IT stakeholder because the technology can get complex. Since the goal is to develop a robust technical system with minimum changes, it is paramount to get the architecture off to a correct start.

At the top level, the team leader is responsible for overseeing all areas of HCP spend, identifying the applications that support these activities, and defining what expenses need to be consolidated and reported from each system. For the sake of due diligence, it is important to engage the steering committee at critical milestones.

It is very clear to note that creating a flexible solution that will accommodate changing laws and requirements is paramount. For global companies, it becomes more complex because they may have to report HCP spend in international locations as well. While the rules and requirements for international HCP spend have not been fully defined and documented, companies might benefit from developing a rudimentary reporting system to collect this data. This will ensure that a run-up to such a system, when the time comes, will not be too long. It is also important to play close attention to data privacy issues & technical security that may arise in countries outside of the US. We will look at some of these points in the next section.

C) Research Applications to Meet Requirements

There are many applications that assist with data capturing and spend reporting to support the business processes & needs relative to PPSA requirements. Before looking into various systems, companies must understand the various spend categories and the key fields that will be required for reporting to meet compliance. Some of the key areas that factor as inputs towards HCP spend are shown below in the figure.

Figure 5 – Systems that contribute to Sunshine Act spend data

The following steps will help a company understand the entire spend cycle and its effect on existing reporting structures:

1) Note all the spend activities where there is an exchange of material, products, samples, information and gifts with an HCP (e.g.: sales call, promotional campaigns, trial activities)

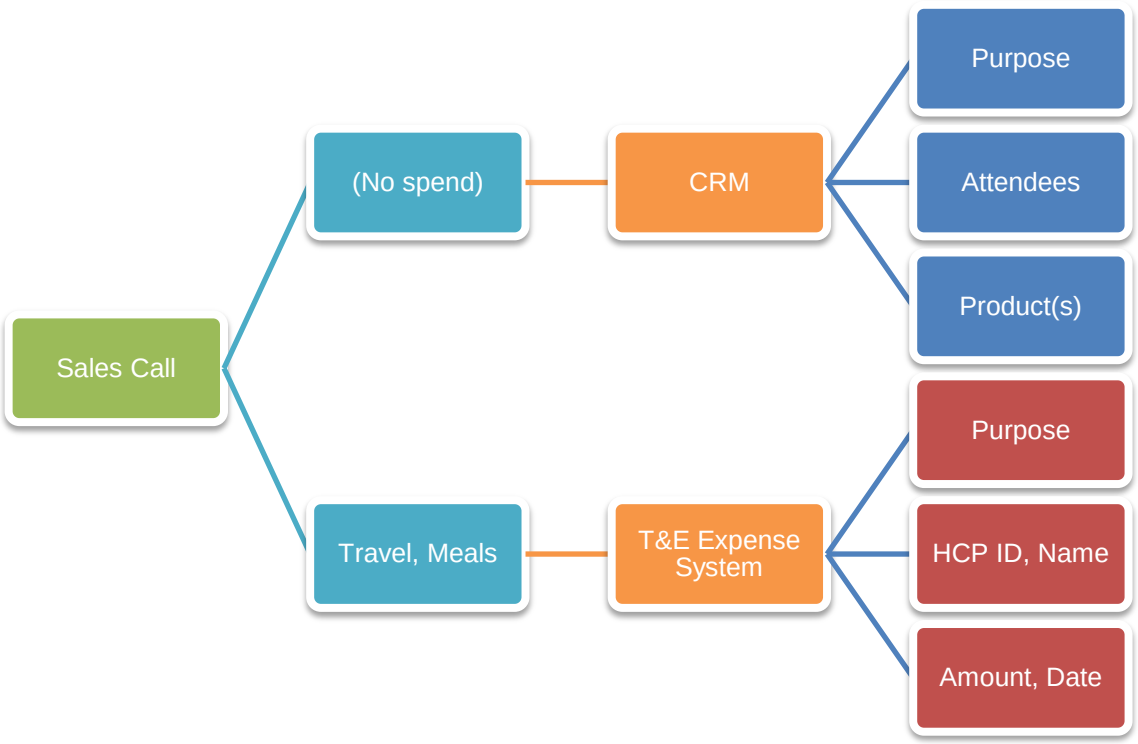
2) List all the spend types associated with the activities (e.g.: T&E expenses, fees)

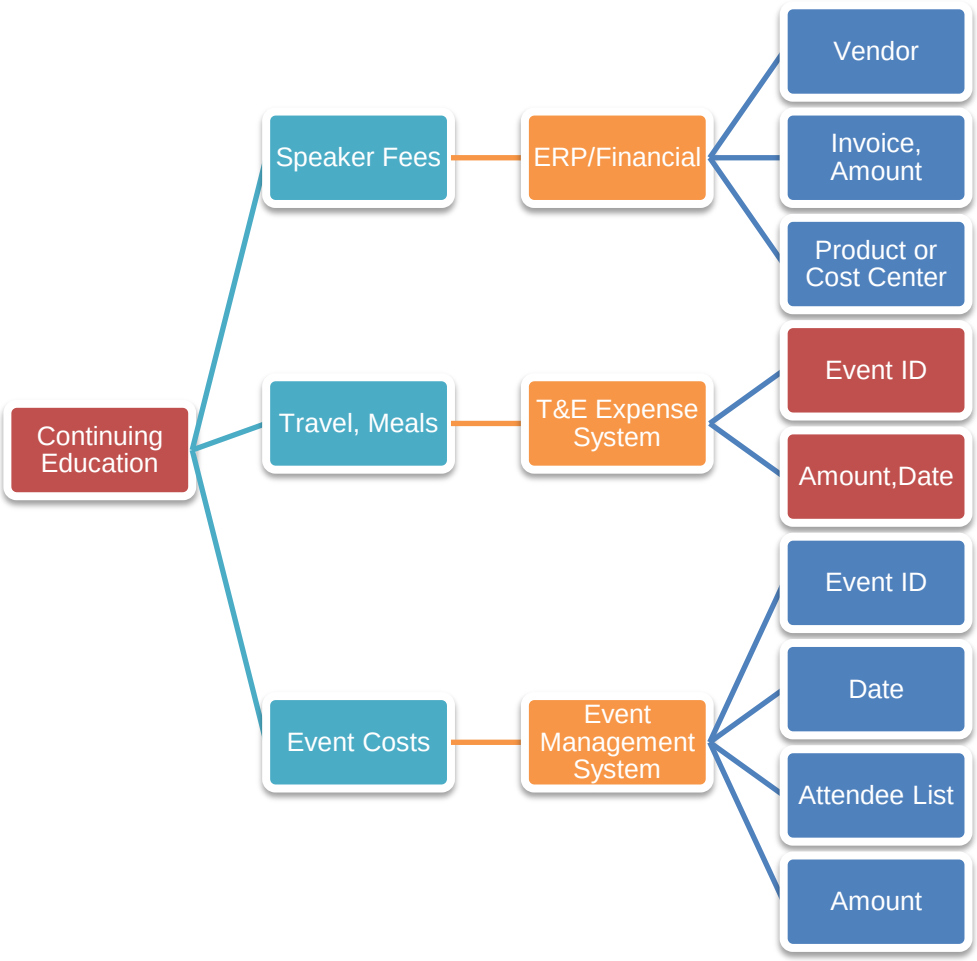
3) Compile a list of applications that track the various areas of spend (e.g.: T&E reporting system, CRM)

4) Make a comprehensive list of PPSA specific reportable elements that are part of each system (e.g.: who are the attendees, nature of expense, product, payment amount)

Here are a few process oriented examples of how relevant data is collected from spend activities and how the data collecting application provides reporting elements.

Figure 6 – Interaction between the application, process and final data





Once the company has a grasp of how the different applications report parameters related to HCP spend, it needs to understand how these different parameters are tracked and reconciled in multiple places. For example, meals at a tradeshow can be tied to the event management system as well as the T&E expense reporting system. Since both input areas are valid, they must reconcile at the reporting stage.

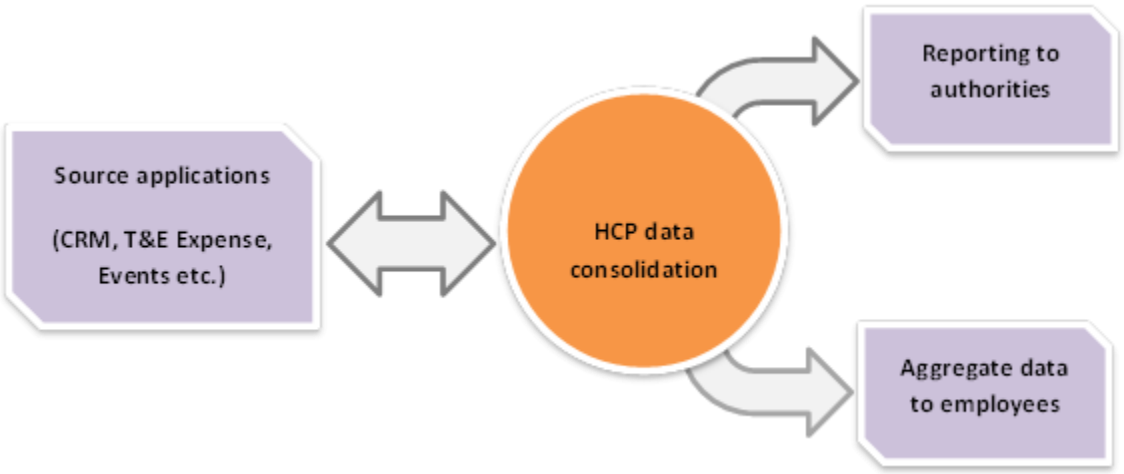
While the PPSA requirements are standard & defined, it is the company's existing processes, procedures and systems that can become complex when adapted to report HCP spend. Companies must find the path of least resistance towards making these applications conform to reporting HCP spend. Towards this, the company must determine gaps between the current state and the required future state.

D) Update Business Processes & Systems

To meet reporting requirements, companies will need to modify their existing applications in order to track HCP spend. The gamut of changes to these applications depends on the complexity of the company's current business processes.

These modified applications must allow users to allocate spend to specific HCP parameters in order to provide complete and valid data. Many companies use a centralized database to store and track this data instead of doing it through the source applications which can become very cumbersome. At a very basic level, typically, companies should follow the process as shown below in the figure.

Figure 7 – Typical process to aggregate spend data



In order to report spend accurately, companies must use unique identification numbers for each HCP. Typically, companies use the Specialty and National Physician Index Number (NPI). In addition, companies can choose to assign unique identification numbers that can be used in conjunction with the NPI.

The source applications can be modified to allow the users to add data fields or enter from NPI lists to track attendees thereby creating the ability to allocate spend to the appropriate HCP. Additional features include adding the ability to search, add, modify and delete lists as required.

How to allocate spend to HCPs?

The fundamental method of allocating spending to an HCP is the same – a company's business processes must allow users to aggregate all spend for each HCP and be able to report it. For this, companies must update their business processes and systems to be able to accurately aggregate and report all spend for each HCP.

Regardless of the approach used, companies must maintain an HCP master record. This will allow companies to accurately report the data. Many 3rd party vendors offer HCP lists that can be purchased. Note that even if these lists are purchased and used, care must be taken to ensure that the records are relevant, updated and frequently maintained.

Due to fast approaching regulations, companies are quickly moving towards a short lead solution that allows them to link various areas of spend directly to the HCP. For this, companies provide the list of HCPs and attendee data into the various corporate wide applications and the employee selects the respective attendee name in each system.

In this method, reconciliation and counter verifications become the key points. If the attendee is repeated in several places, care must be taken so that multiple entries are avoided.

A way to avert this situation is to clearly define and communicate the business processes and areas of spend. For example, spend related to T&E must be submitted and managed only within the T&E system. Planning & meeting related spend must reside only within the meeting system. Both of these systems may recall the same attendee/HCP but the allocation of spend have clear lines of demarcation, thereby avoiding confusion. *It is very clear to see that utilizing the right tool in the right places becomes critical.*

Is purchasing an HCP list a good option?

The short answer is yes. The broad range of parameters needed to identify every HCP accurately, such as NPI, address, name etc. makes it a very effective investment for companies to procure a list. Of course, the list must be valid, frequently updated and guaranteed to be free of errors.

Note that in many cases, the various internal systems may also host relevant and valid HCP data that can be used as a starting point. The places to look would be -

1. CRM systems
2. T&E Expense Management System with all attendee data
3. Accounts Payable notes and data that provide customer information

Typically, companies choose to augment their internal existing data with various listings of HCP data obtained externally. This creates a comprehensive list.

How to resolve data issues?

Once the data has been captured, there must be a verification process to ensure the validity of the data before it is approved. The two main areas to look for are:

Spend related errors – This can happen when a user makes a mistake during data entry. To rectify this, there must be an audit and error checking mechanism that will flag potential issues. To resolve the issue, the employee should be contacted and the data should be modified in the central reporting system.

For example, if a user enters the wrong number of attendees for an event in the T&E system, the managers and stakeholders must decline the expense report and request changes to be made. These changes must include detailed comments about the attendees so that it can be verified. Once all the information is available, the report is approved and the data is sent to the central reporting system.

HCP record issues: When there are manual additions and modifications to an HCP's information, there are chances of errors. To combat this, companies must utilize a process to verify the HCP information with the actual internal or imported data. The most efficient way to tackle this is to require manual additions to undergo a verification process with the central list.

This will typically include a match of the NPI, name, address etc. with the central HCP record. By maintaining a cross reference process that links the new record to the master HCP record, the verification process will be bypassed if the record is selected again. It is also important to have a logging mechanism where changes made are recorded in a log.

E) Conduct Change Management Analysis

The final and equally challenging aspect of complying with the Sunshine Act is to change employee behavior towards achieving compliance.

Getting everyone on the same page

The first stage of change management is to keep the various stakeholders, teams and suppliers on the same page. This can be accomplished by having regular meetings and providing the team with the latest updates related to the Sunshine Act.

All the business unit leaders must have the 30,000ft vision towards understanding the reporting requirements while not getting caught up in the system implementation details. Although there is a fine balance between the development effort and implementation time, with the clock ticking, more time must be allocated up front towards creating a holistic, scalable and adaptable solution. This will make it easier for companies to meet the requirements in the US and globally as new laws are enacted.

Changing employee behavior

All employees must be aware of the new regulations upfront and understand that the company is committed towards meeting the new rules to be compliant. This will help set the stage for the imminent changes as well as clarify company-wide expectations.

Once the new processes are defined and system solutions are incorporated, companies must provide regular compliance training for the entire organization so all employees understand the legal and financial ramifications of not meeting compliance. Companies must also educate employees on the 'changes-to-come' and not allow those aspects to become elements of surprise. This is the leading cause for employees to inadvertently break compliance.

In addition, many companies must also educate and train employees on the convergence of compliance/HCP tracking along with system-wide applications such as the expense reporting system, CRM etc. It is important for employees to understand how data submitted by them through these systems can affect compliance reporting.

All form of communication and policies must come from the top. This will relay the importance & urgency of the initiative. It is also important for employees to understand that these solutions were developed to be cross-functional. Documenting interactions and data with each HCP requires considerable effort and employees must be fully on-board for the initiative to be successful.

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