HEALTH MARKET SCIENCE®

Preparing for the Sun to Shine

A How-to Guide for Creating RFPs for Aggregate Spend Compliance Solutions

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"If your company does not yet have any efforts or plans in place, please explain why not."

Sen. Charles Grassley, R-Iowa
Re: Physician Payment Sunshine Act

Why should you care?

The likely to pass Physician Payments Sunshine Provision (Subtitle D) of the pending US Healthcare reform bill mandates the disclosure of promotional and other spend by life science companies with medical providers.

- Who: The manufacturer (pharmaceutical, biotechnology, medical device) or distributor
- What: shall submit recipient's name, business address, physician specialty, national provider identifier, value, date, name of the related drug, device, or supply, cash, etc.
- Where: for the entire United States. This is significantly broader than the current several states and District of Columbia with similar laws
- When: By March 31, 2011 and annually thereafter

What happens if you don't?

Civil penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value limited to $1,000,000, or, if greater, 0.1 percentage of the total annual revenues of the manufacturer

Given that implementation of systems and updating processes consumes between 3 and 12 months, 2010 will be an active time for life science companies seeking to address this legislation. To assist in this endeavor everyone must face, we created this eBook as a free guide to help the industry in their efforts to frame the entire problem and evaluate alternative solutions.

You Are Not Alone

Currently, aggregate spend compliance for most pharmaceutical and medical device companies consists of processes whereby either individuals manually collect and integrate spend information or individuals manually stitch together disparate systems for the filing deadlines of each state or DC.

> *One of our clients distributed a spreadsheet template to each department and its service providers where spend on healthcare professionals (HCPs) had been identified. The information was then culled from various sources (e.g. Grants, Travel and Expense, Meeting Management, etc.) and entered manually into the spreadsheet. The result was a hodgepodge of missing data fields, transposed or incomplete HCP names and inaccurate reporting resulting from varying interpretations of instructions.*

These approaches are inadequate to meet the needs of ever-changing legislation and disclosure requirements. Companies also miss the opportunity to address internal business and compliance needs. For example, a complete aggregate spend solution adds the capability to optimize promotional spend and monitor adherence to internal compliance SOPs and call plan directives.

Certainly, a solution requires a software system as its core; however, it also requires:

1. An extensive exploration of spend sources
2. Business rule interpretation based on the pertinent laws and regulations
3. Translation of business rules into system rules
4. Accurate customer data
5. A simple user interface
6. Seamless data aggregation
7. Customizable reporting and disclosure

A Bird's Eye View of an Installed Solution

There are six key areas that define how an organization aggregates spend and generates reports:

Aggregate Seamlessly capture disparate data from all spend sources with minimal IT support.

Validate Dr. Smith, Mike Smith, M. Smith, Michelle Smith; same person? Is Dr. Smith, who incurred spend reported in the travel & expense system, the same person as M. Smith, who was a speaker in the meeting management system? Is he licensed in more than one state? Your solution better link these expenses and validate quickly and accurately.

Interpret A service provider sends you a list of speaker program attendees, but includes attendees who are not reportable for state A, but are reportable for state B. You need a flexible solution that can interpret this data into information the legislation requires.

Track Without instant access to your spend data from a variety of data points, how effective is your monitoring program? Without the ability to peer inside your spend at a moment's notice, how can you ensure you are out in front of potential problems?

Alert You have an annual spend and visit frequency limit for certain consultants and speakers: how does your field know—in real time—when they are approaching those limits?

Report Your solution must provide accurate reports not only for external requirements, such as state and federal HCP spend reporting, but also for internal metrics.

Asking the right questions

We know that the vendor selection process can be challenging, so we've provided a list of key questions to help you construct a Request for Proposal (RFP) or a Request for Information (RFI).

Product Vision

- How will planned technology changes enhance the performance and longevity of the application infrastructure?
- What is the long-term technology vision of your product?

Logistics

Determine how the vendor proposes to manage the project, from timelines to project managers.

- Describe the project management process, both internal and vendor-based, that will guide the process.
- Define milestones and success metrics; include schedules, showing major tasks, parallel activities, milestones, and checkpoints.
- Provide a description of any deliverables provided for each stage described below.
- Provide résumés of the personnel who will be assigned to this project.

Operational readiness

A successful and timely project requires buy in and cooperation at every stage and at every level. Your vendor should share details for winning internal support.

- Provide a detailed outline of the process by which your organization would analyze our current business processes. Please provide specific examples of the resulting analysis and planning documentation deliverables. Include how you will assess our baseline level of readiness to address legislative requirements.

- How do you propose to create buy in to successfully integrate the solution throughout the organization?
- Describe how your plan of action minimizes the impact on the business.

Exploring spend sources

As the adage goes…*Garbage In*, *Garbage Out*. Discovering your spend sources is a complex task. Your vendor should describe how they approach this phase and what resources they will devote to the process.

- Describe, in detail, your process for discovering sources of HCP spend.
- What resources will you devote to this phase? What resources will be required from us?

Business rule interpretation

Your solution must allow you the flexibility to establish business rules according to *your* interpretation, keeping you in control of your policies.

- Do you offer user configurable business rules? If so, describe the process of defining business rules, including creation, maintenance and update flexibility, etc.
- How do you interpret state/federal legislation?
- Does your solution offer state/federal legislation interpretation? If so, is it customizable?
- Does your solution include a Reporting Policy? What resources do you devote to this process?
- Does your solution allow us to update our business rules without interacting with you as the vendor? What about adding new states?

Translating business rules into system rules

Once your business rules have been defined, the aggregate spend database must be configured to reflect these rules. You will want to ensure that these system rules, once set up in the solution, are customizable by you,

to accommodate changes in the legislative landscape or in corporate policy.

- What process will you use to ensure the business rules are actualized within the aggregate spend solution as its system rules?
- Are the system rules customizable by us, without input from you as the solution service provider?

Accurate customer data

Guess what? it's not just software! One of the biggest hurdles to achieving disclosure compliance is actually a data challenge. Most companies today maintain multiple systems to facilitate and track HCP expenditure. Because these systems do not contain a common identifier for HCPs who are listed across multiple non-integrated systems, there might be five variations for the same Dr. Robert Smith: R. Smith MD, Bob Smith, Dr. Smyth, etc. Same guy, different names. This same doctor might also have multiple addresses associated with his name across systems and he may practice in multiple states. How, then, do you accurately track spend related to Dr. Robert Smith? And when you are close to reaching the limit for a HCP in a state, do you know it…or is your spend spread across 4 different records that are actually the same HCP?

As the life science industry faces new reporting requirements, the initial challenge for any aggregate spend solution is to create a clean customer database, sometimes referred to as a customer master. A good customer master will provide detailed and accurate customer data across systems, including those used by your service providers—don't forget, they will feed spend data into your solution…and it may be ugly.

Your potential vendors must be able to describe how their solution will assure that data for HCPs and HCOs will be cleansed, validated, matched and properly assigned by category in accordance with current and future state and federal laws, as well as internal policy.

- Does your solution require us to have an existing customer master?
- Does your solution include an integrated HCP customer master that will enable us to incorporate spend on HCPs who do not already exist in our current customer data?
- If your solution incorporates an HCP customer master, how is it managed between clients?
- How do you address duplicate entries for individual HCPs?
- When HCPs are merged after they have been identified as duplicates, how does your solution integrate the spend data that has already been entered against the individual?
- Explain your abilities to link spend recipients brought in through spend feeds to HCPs in the customer master.
- Explain your matching process. How does your solution deal with records that do not automatically match? What about duplicates?
- Can your solution automatically link to data cleansing and scrubbing services? If so, does it reach accuracy of 95%?
- Describe how your solution resolves data discrepancies between various sources of spend.
- Does your solution also track spend across healthcare organizations with an HCO customer master?
- Does your solution provide relationship linkage between HCPs and healthcare organizations?
- Can one or more employees be recipients of spend?

Configurability and flexibility

The application should be as configurable and flexible as possible. Even if you don't think you will need these features now, you may appreciate them as your organization becomes more experienced with the solution. There are several different levels of configurability and flexibility to consider, all of which should be "transparent," so they will not be confusing should you need them in the future.

- Describe any limitations related to your system's ability to handle data acquisition (high number of spend sources, high volume, etc.)
- Can new service providers be added through the customer interface? Explain that process.
- How does your solution set up and integrate data sources? How quickly can a new source be added?
- Does your solution offer a central interface that permits modifying the application terminology? For example, some organizations call business objectives "goals," some call them "CFOs" (for critical few objectives).
- Is your solution expandable to ex-United States operations? If so, please describe the process for doing so.

Simple user interface

- Is your solution's interface customizable?
- In addition to the receipt of data feeds from various sources of spend, does your solution incorporate a user interface that enables the manual entry of data?
- Does your solution include an interface for service providers to directly upload, enter, and manage spend with little or no interaction from us?
- Would you provide a demonstration of the interface? Screenshots?

Seamless data aggregation

- Describe how your solution enables us to capture, aggregate, track, and report expenditures in the following areas. Please append this list with any additional areas that you feel are missing, to demonstrate your company's expertise and understanding of the scope of this effort.
  - Home office and sales force expenditures to HCPs[1] (e.g. sales force, Medical Science Liaisons, marketing, Managed Markets, Clinical Affairs, Grants, etc.). Include:
  - HCP compensation for speaker and speaker training activities
  - Consulting honoraria
  - Meals provided to HCPs by home office personnel
  - Premium items, including those distributed at local, regional, and national conferences
  - Compensation for advisory boards
  - Grants
  - Continuing Medical Education programs
  - Clinical trial-related spend
  - Service provider payments to HCPs
  - Promotional and advertising expenditures
  - Direct-to-consumer advertising by product

[1] Include physician residents and prescribing non-physician HCPs

Reporting and disclosure

Your Aggregate Spend Solution should provide you with the tools you need to accurately report HCP spend in response to state and federal law. It should also give you the ability to generate customizable reports for use internally.

- Describe the reporting function of your solution.
- Will your solution enable us to identify, pull, and prepare reports that meet the specific requirements for individual states, as well as federal requirements?
- How are existing reports modified when necessary to meet changing regulations?
- Are the reports customizable to address our specific compliance needs?
- Describe all report limitations (e.g., number of records, scrolling across multiple pages, etc.).
- Describe all ways in which reports may be viewed.
- Does your solution include a real-time alert function for spend thresholds? For visit frequency?
- Do you offer a planned versus actual function for expense planning and alerting?
- Can all available alerts be grouped into a single email?
- Do you offer an ad hoc query tool?
- Following report submission, do you have the ability to archive all reports and supporting documentation for review for audit purposes?
- Do you offer the ability to store each filed report for audit purposes? If so, explain the data archive process.

Summary

Crafting a comprehensive RFI/RFP is not as daunting as many consulting firms make it out to be. If you have a clear understanding of the current reporting requirements and have assessed your organizational readiness, the technical requirements are straightforward.

Just remember, the biggest challenge of any aggregate spend solution is coupling accurate HCP and HCO profiles with a robust system for aggregating all the disparate spend sources. You can build the best car in the world, but without clean fuel, you're not going to get far, no matter how accurate your roadmap. This core foundation is the key to compliance especially when the sun is shining.