
**Oracle: Providing health care provider spend compliance and transparency
for life science companies**

A White Paper

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Introduction

Legislation in several states and more recently, at federal level, requires life science companies to disclose financial arrangements with healthcare providers. The premise of the legislation is that there is a potential or perceived conflict of interest in some of the shared financial interests. The overall goal of the legislators is to both regulate certain activities of life science companies and require transparency for a range of interactions between health care providers and life science companies.

Reporting requirements in several states (Vermont, Massachusetts, D.C., Maine, West Virginia, Minnesota, Nevada, California) have been in place for a few years but the recent federal "Sunshine Act" requires companies to report to the Secretary of Health and Human Services by March 31, 2013 for all defined transactions from the 2012 year. The federal legislation does not pre-empt the states' requirements, which continues the differing reporting timelines, frequency, and content for reporting.

Current approaches

Current state reporting solutions have often been implemented incrementally as individual states passed laws with differing requirements. The state laws focus on one or more of the following goals: bans on gifts and other financial benefits offered to physicians, gift and financial transaction reporting requirements, and/or adoption of codes of conduct. In addition, some states have regulated manufacturer advertising, industry-sponsored clinical trials, and basic research. The variety of information has made it a challenge to collect and summarize the various data sources.

To achieve compliance, several sub-optimal approaches have been taken, including:

- Reps manually re-entering transactions
- Extracting from current systems using BI tools
- Outsourced reporting to service providers
- Outsourcing integration to service providers

Existing approaches have several drawbacks:

- No single view of physicians and spend
- No benefit other than immediate compliance
- Lack of integration across the lines of business (Legal, Regulatory, Sales, Marketing)
- Lack of integration with CRM processes
- Expensive and "locked into" service providers

Extending current tactical solutions may also result in data quality and completeness issues that could have an impact on company reputation when the information is made available to the public.

Full compliance

Many life science companies are now looking for a more strategic approach that incorporates systematic processes to achieve compliance. The core of a strategic solution is capturing all required data consistently and ensuring it can be consolidated for the mandatory reporting. This can involve modifying current business processes to capture the necessary information, identifying health care professionals and affiliations, and reporting all the relevant transactions.

Companies are also evaluating the potential of providing payments history information when new payments are being planned. This approach might also include a workflow approval process based on company-specific aggregate spend targets.

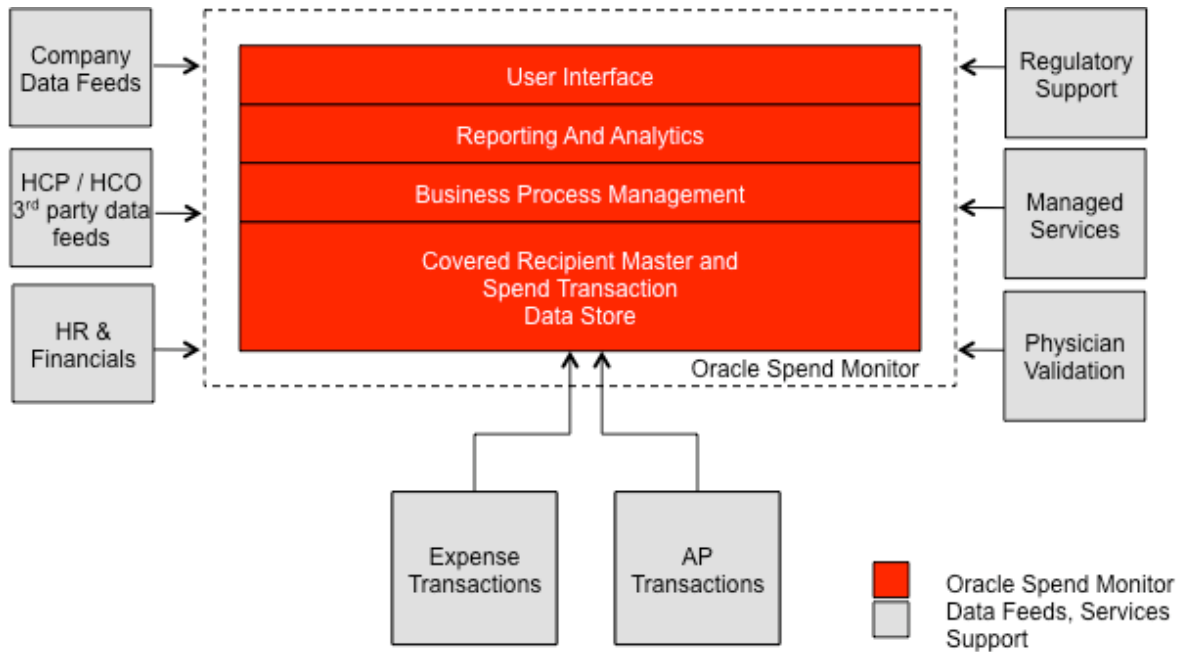
Moving from compliance to transparency

Some life science companies have longer-term aspirations to move beyond the details of compliance to existing legislation. The foundation that is built for compliance could provide a platform for communicating both internally and externally the company’s commitment to transparent and ethical business relationships in the healthcare system. The information base used for reporting compliance could be used to define improved business processes and public engagement.

Oracle’s Spend Monitor Solution

The Oracle Spend Monitor solution delivers technology and services to comply with the federal and state aggregate spend requirements. Combined with regulatory, project management, and technical delivery expertise, the comprehensive and flexible solution has a modular design that can be fully implemented as a complete solution and also can be integrated into a company’s existing environment and deliver the benefits that are required.

The following diagram summarizes the integrated Oracle Spend Monitor solution along with the modular design approach.



Key elements of the Oracle Spend Monitor solution

Oracle Spend Monitor is a set of pre-packaged and integrated products, services and federated data feeds that:

- A. Incorporates existing customer master files and creates a validated health care practitioner identifier across source systems and standardized 3rd party data feeds. A rigorous gap analysis and requirements evaluation is performed with each customer based on deep regulatory and technology knowledge and experience. This will provide a high quality foundation for the monitoring and reporting
- B. Captures all required HCP spend data from all necessary company core financial, payables, HR, and operational systems into a consolidated database. Versatile data transfer processes are defined, validated and executed to align with the source data update cycles.
- C. Produces robust reporting and analytics required for all state and federal requirements as well as providing highly flexible business intelligence functionality for all stakeholders in the company.
- D. Maintains and updates rules for mandatory reporting content and schedules. Regulatory expertise is available for interpreting requirements in legislation and implementing appropriate business rules.
- E. Provides robust internal auditing and monitoring reports. State-by-state dashboards are incorporated into the solution as well as internal data quality processes and compliance alert reporting are built into the solution. Company workflow approvals can be implemented to actively manage planned spending. Proactive intelligence can be applied to detect problems before they occur, such as an unusually high number of new HCP's or HCP spend above a peer average.
- F. Includes options for managed services to ensure high quality regulatory support and technology hosting as needed. The solution is updated as needed for new legislative requirements. External hosting can provide the flexibility to support the necessary technology with high quality expertise. The complete set of services can also be integrated with existing company functions. In addition, training is provided for the essential knowledge and skills required to manage and use the system.

Comprehensive State and Federal Reporting of Spend Transactions

Created	Date	Status	HCP Last Name	HCP First Name	HCP ID	NPI	Description	Spend Type
3/15/2011 9:44:52	2/15/2011	Remediation	Sax	R	1-4627L		Knee Replacement	Payment
3/15/2011 9:30:02	2/15/2011	Acceptable	Dohi	Amar	1-19L2X	9127829636	Knee	Payment
3/15/2011 9:28:18	2/15/2011	Acceptable	Dohi	Amar	1-19L2X	9127829636	Speaker Programs	Payment
3/15/2011 9:28:10	1/4/2011	Acceptable	Dohi	Amar	1-19L2X	9127829636	Speaker Programs	Payment
3/15/2011 8:32:57	2/3/2011	Remediation Require	Sax	R	1-4627L		Heart Valve Royalty	Payment
3/14/2011 12:52:38	2/2/2011	Acceptable	Sachs	Roger	1-46R93	7812302034	HCP Services	Payment
3/12/2011 6:47:34	3/7/2011	Remediation Require	Selak	Adnan	1-3HQ2B	9123781230	HCP T & L	Payment
3/8/2011 12:27:01	2/17/2011	Unacceptable	Selak	Adnan	1-3HQ2B	9123781230	Product/Service Donation	Payment
3/4/2011 12:54:29	1/15/2011	Acceptable	Prasad	Val	1-1K3FT		Medical Advisory Board	Payment
3/2/2011 5:41:36	3/15/2011	Acceptable	Babu	Suresh	1-10B2U	7129311567	Investigator Sponsored Study (Desc from SS 5:42
3/2/2011 7:44:59	3/1/2011	Acceptable	Prasad	Val	1-1K3FT		Product Training (other)	More Consulting
3/2/2011 7:44:58	3/1/2011	Acceptable	Prasad	Val	1-1K3FT		Speaker Programs	Consulting
3/2/2011 7:44:56	3/1/2011	Acceptable	Prasad	Val	1-1K3FT		Royalties / License Fees	Dinner
3/2/2011 7:44:57	3/1/2011	Acceptable	Prasad	Val	1-1K3FT		Royalties / License Fees	Lunch

HCP Matching

Value	Transaction Date	Nature of Payment	Description	Change Reason	Do Not Report Co Error Code	Medication Name	Payment Nature	Primary Purpose	Product Market	Target Audience
	2/15/2011	Consulting	Knee Replacement		Missing NPI			Medical Advisory Bo		
	2/3/2011	Consulting	Heart Valve Royalty		Missing NPI			Royalties / License F		

Spend Transaction Remediation and Audit Trail

The screenshot shows the Oracle Spend Transactions Remediation interface. At the top, there are navigation tabs: Spend Transactions, Spend Analytics, Remediation, Certifications, Disputed Transactions, Spend Thresholds, HCP Data Management, and HCD Data Management. The main window displays a table of remediation transactions with columns for Created, Date, Status, Type, Purpose, Amount, HCP Last Name, HCP First Name, HCP Id, NPI, Description, and Spend Type. Below the table is a 'Detail' section with various input fields for SS Category, SS Do Not Rpt, SS Nbr Event Ref, SS Oth Nature Exp Text, SS Product 1, SS Resubmission, SS Trade Secret, SS Category of Payment Id, SS Facility, SS Medium Name, SS Org Sub Date, SS Oth Purp Exp Text, SS Product 1 Type, SS Sec Purpose, SS Cvd Recpt Id, SS Medium Type, SS Oth Desc Nature Text, SS Oth Recpt Type, SS Recpt Type, SS Target Aud, SS Verf OOS, SS Desc Gift Text, SS Nature OOS, SS Oth Desc Sec, SS Oth Sec Purpose, SS Resub Desc, SS Trade Sec Exp, and SS Type of Activity. At the bottom, there are fields for HCP Last Name, HCP Account Name, and SS Position Title.

Insightful Analytics

The screenshot displays the Oracle Business Intelligence dashboard for 'Aggregate Spend'. The dashboard includes several charts: a 3D pie chart for 'Total Spend' by state (District of Columbia, Maine, Massachusetts, Minnesota, Vermont, West Virginia); a bar chart for 'Total Spend' by Transaction Type and State Id; a horizontal bar chart for 'Spend by Purpose' (CONSULTING, EDUCATION, MARKETING, SPEAKER FEE); and a stacked bar chart for 'Total Spend by Payment and State' across categories like BOOK, CASH, DONATION, ENTERTAINMENT, FOOD, LODGING, OTHER, and TRANSPORTATION. The dashboard also features a search bar, navigation tabs, and a status bar at the bottom.

Implementation Scenarios

Oracle Spend Monitor can be deployed in a variety of implementation scenarios to optimize your return on investment on current and planned IT investments:

Complete Spend Monitor solution

A complete solution for aggregate spend can be deployed with all the services and technology of the Spend Monitor solution, including customer master, business intelligence, workflow and approvals.

Value of Oracle solution

- Robust functionality to meet aggregate spend requirement
- Provides a mature customer hub to core company applications (sales, marketing, clinical)
- Provide foundation for future master data management requirements

Spend Monitor integrated to existing customer hub

The existing customer hub and data sources will be kept intact and Oracle Spend Monitor solution is deployed to ensure high quality data feeds and produce the required reports.

Value of Oracle solution

- Robust functionality to meet aggregate spend requirement
- Well-designed interfaces to all sources of HCP spend
- Ability to implement key requirements and integrate with existing customer hub

Spend Monitor integrated to existing customer hub and other data feeds

The existing customer hub can be used as one of the feeds into the Spend Monitor solution. For example, their customer hub may contain partial information and the effort required to modify it to meet aggregate spend requirements is costly or would not meet the required timeline.

Value of Oracle solution

- Implementation speed / cost
- Robust functionality to meet aggregate spend requirement

Spend Monitor in conjunction with customer's analytics toolset

The customer analytics existing tools can be interfaced to Oracle Spend Monitor. The core aggregate spend reports will be produced by the Oracle Spend Monitor solution.

Value of Oracle solution

- Deep expertise in aggregate spend requirements and future changes.
- Modular design can be integrated with company analytics tools

Spend Monitor including use of Oracle BPM engine for workflow & approvals

A workflow and approvals solution is part of the customer requirement.

Value of Oracle solution

- Use a full-function business process management engine to manage spend approvals
- Deep expertise in aggregate spend requirements and future changes

For more information, please go to www.Oracle.com/Lifescience