

WHITEPAPER

THE SUNSHINE ACT: COMPLIANCE IN EXPENSE REPORTING

With the Physician Payments Sunshine Provisions in health care reform legislation, the federal government joins six states in mandating the reporting of expenditures by life science companies on healthcare providers (HCP) identified with National Provider Identifiers (NPI). The Physician Payment Sunshine Provisions were included in the Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002), referred to in this document as the Sunshine Act, which was signed into law on March 23, 2010. Starting on January 1, 2012, all U.S. manufacturers of drug, device, biologics and medical supplies covered under Medicare, Medicaid or SCHIP must record all transfers of value on an annual basis. This information is to be reported to the US Department of Health and Human Services by March 31, 2013 and annually thereafter. HHS will post the information provided on a public website.

The law requires disclosure of payments, whether cash or in-kind transfers, to all covered Health Care Professional (HCP) recipients including:

- Direct compensation
- Food
- Entertainment
- Gifts
- Travel
- Consulting fees
- Honoraria
- Education
- Research
- Grants
- Charitable contributions
- Royalties or licenses
- Current or prospective ownership or investment interests
- Compensation for serving as a faculty member or as a speaker for a continuing medical education program
- Any other transfer of value as defined by the Secretary of Health and Human Service

Face-to-face sales and promotional activities directed toward HCPs, known as "detailing," is the largest industry marketing segment after expenditures on pharmaceutical samples. Where a payment is related to marketing, education, or research specific to a covered drug, device, biological or medical supply the reporting companies will be required to report:

- Name
- Business name
- Address
- National Provider Identifier
- Value of the payment or transfer of value
- Dates of the payments or transfers
- Description of the form of payment or transfer of value

PROBLEM STATEMENT

A company affected by the Sunshine Act is likely tracking spending associated with food, entertainment and gifts incurred in the direct marketing to HCPs as part of their expense reporting process.

The challenge in tracking these types of expenses to the level of granularity required by the provisions of the law is the large volume of data and complexity associated with breaking down detailing costs. Another challenge is managing the exceptions to the rules and state-specific requirements.

The potential for poor data quality, due to tracking many small transactions divided by a large list of recipients, poses a risk in operational effectiveness as well as compliance.

Clear and consistent data is key to assisting the healthcare industry in managing the "burden of reporting" posed by the Sunshine Act. This consistency allows for auditing as well as management of the detailing process itself.

For each failure to report, fines of up to \$10,000 will be applied, not to exceed \$150,000 annually. For each knowing failure to report, fines of up to \$100,000 will be applied, not to exceed \$1,000,000 annually.

MEETING NEW LEGISLATIVE REQUIREMENTS

Satisfying the provisions of the Sunshine Act has prompted life science companies to look at alternatives to current expense reporting processes. Manual reporting, or a system that does not allow for managing data to the level required by law is inadequate in supporting not only the aggregation of total data and other compliance requirements, but also the effective operation of the business.

The output to HHS is required to be electronic, searchable and easily downloaded. An expense solution that supports these requirements from the initial input step of the process allows the business proactive control and management, not only of the data itself, but of the direct marketing process as a whole.

Control of the reporting process is paramount to ensure accuracy and auditability of the data and meeting the new legislative requirements. A tool that allows management of the local delivery process before the direct marketing expenditure is incurred will not only help compliance, but also support the efficiency of the detailing process itself.

DATABASICS' SOLUTION

DATABASICS offers enhanced functionality for tracking policy and reporting to allow compliance with the Sunshine Act. This functionality is part of the Expense reporting process for expenditures associated with direct marketing to health care providers.

The application provides a solution that simplifies the tracking of expenses incurred in the direct marketing to physicians down to the level of detail required by federal law.

The application also meets individual states' additional rules and threshold limits. DATABASICS' policy engine supports local management of the HCP relationship through a provision of policy enforcement on the end-user interface. The application's reporting tool allows the customer to define reports on an ad-hoc basis and make use of standard aggregate spend reports.

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The policies and reports can be easily built and maintained by the customer's application administrator and can be managed on a specific level of the organization structure (including region, or individual users), as well as on the activity level (i.e., product or customer). The application also offers robust audit functionality that allows management and auditor control of changes, not only of the data itself, but also of the management of the process.

Examples of specific Sunshine Act business scenarios supported by DATABASICS Expense include:

- Policy and reporting functionality help manage those states that do not allow gift giving at all.
- Policy and reporting functionality supports law exemption expenses of less than \$10 for reporting until the aggregate annual total per company (per covered recipient) reaches \$100. At that point all payments (retroactively) must be disclosed.
- The application distinguishes between and validates attendees with NPIs versus other attendees, such as office staff.

Because it is vital for compliance to ensure reporting against unique Health Care Providers with NPIs, a standard DATABASICS implementation can be integrated with a database of HCPs, often held in a CRM system. A typical solution would also include a bespoke data extract to this external system, to allow aggregation of all HCP expenditures in one location for reporting to The US Department of Health and Human Services.

In addition, DATABASICS allows for reporting of all expenditures reported in the application itself. The application facilitates for very flexible parameters of reporting: data can be reported on at a granular level, rolled up for HCPs at multiple locations, or aggregate spending at the practice level using standardized descriptions for the standard payment types.

SOLUTION BENEFITS

Simple Data Entry

The list of healthcare professionals (with their National Provider Identifier) can be loaded into DATABASICS. This allows the application to recognize the name, or other HCP attribute, as the end-user starts typing in a field, simplifying the entry and selection of attendees into predefined expense types. The application also maintains a local list for each individual user's historical attendees, which can be imported to new expenses, further simplifying the process for the end-user.

Attendee Distinction

The application validates the attendees entered against the NPI master list. This validation assists in the accuracy of the data entered and helps distinguish these recipients from other staff in policy enforcement as well as reporting.

Rules and Policy Enforcement

Each customer can configure and enforce policies specific to their needs within the DATABASICS application. These rules may be governed by the policies of the company or by the state in which they do business as well as federal regulation.

Tailored Reporting

Customers can create and manage reports that fit the needs of the company, as well as meeting the requirements of state and federal governments. These reports include:

- Aggregate spend reporting
- Detail reporting by recipient or company
- Compliance reporting

Full Data Integration

DATABASICS supports full integration with existing systems, facilitating valid and accurate data to support the process. These include:

- Simple load specifications for the import of data into DATABASICS
- Tailored data output files to the customer's back-end systems

Flexibility in Meeting Customer Specific Requirements

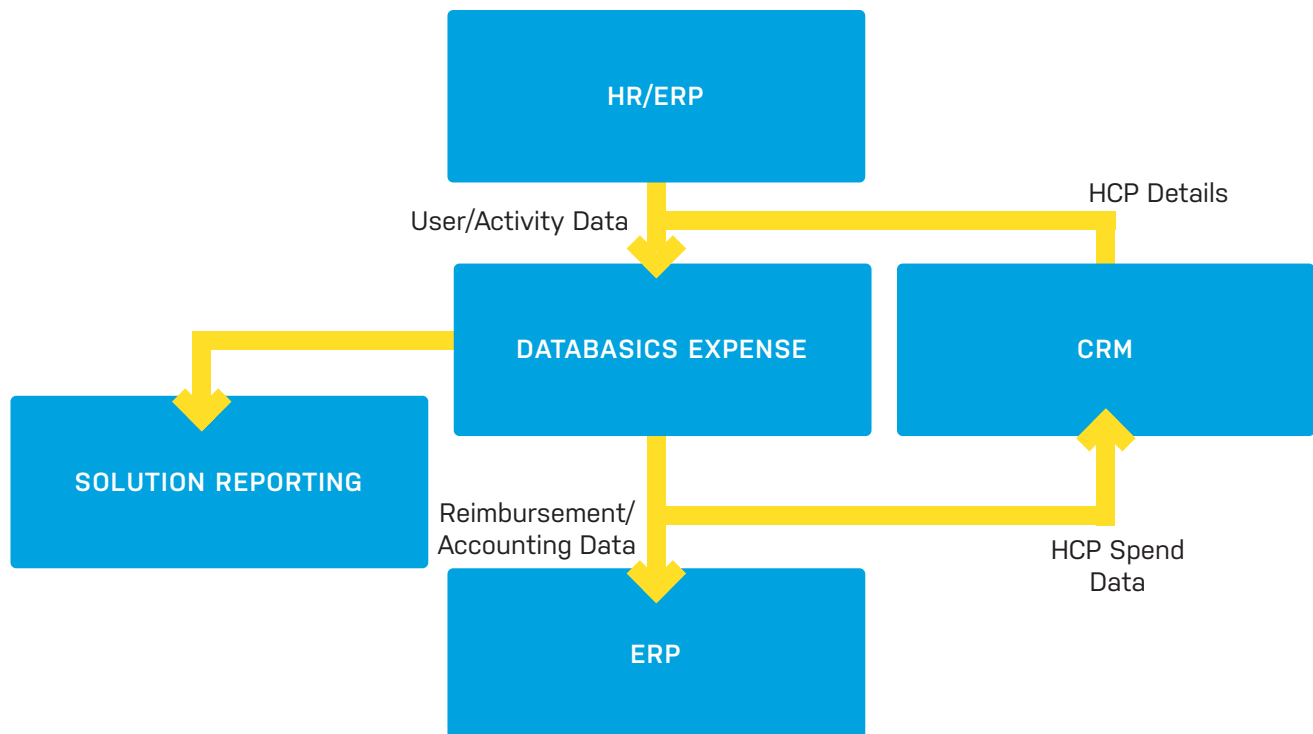
DATABASICS has a long history in meeting customers' specific requirements to fulfill business and compliance needs. This is particularly important in a legislative environment that continues to be developed both on a federal and state level

IMPLEMENTATION

DATABASICS has been providing our best of breed expense reporting solution since 1996 and offers well-established roadmaps to implementing solutions based on our customers' specific requirements.

A typical solution to meet requirements in the Sunshine Act includes data being loaded into DATABASICS from an HR/ERP and CRM system. Data would be extracted to a CRM system for Sunshine Reporting across all types of transfer of value, as well to the ERP system for expense reimbursement and accounting.

In addition to the above, a typical DATABASICS implementation may also include credit card feeds, as well as travel feeds. This facilitates further ease of use for the end user, as well as enhancing the reporting data.



A DATABASICS implementation schedule will be agreed with each individual customer, but should take between 6 and 12 weeks.

SUMMARY

The large volume of data and complexity associated with breaking down expenditure to the level of granularity required by the Sunshine Act makes compliance a challenge for the life science industry. Operational effectiveness and compliance are further affected by exceptions to the rules and state-specific requirements.

DATABASICS Expense offers:

- **Simple data entry:** Allows the field representative to focus on their main objectives of creating awareness of their products, rather than administration.
- **Locally managed, robust policy and reporting engines:** Allows the life science company to meet complex and changing requirements from federal and state agencies, as well as internal requirements.
- **Full data integration:** Supporting compliance as well as operational requirements.

It is perceived that the Sunshine Act has put a "burden of reporting" on our customers. DATABASICS is confident that the change in legislation is also an opportunity for a life science company to more efficiently manage the detailing process, as well as their general operations.



DATABASICS is driven to meet the most demanding time and expense management challenges for organizations throughout the world with a combination of deep expertise, next-gen technology and a focus on the unique needs of each customer. Powered by decades of experience, DATABASICS is in the business of solving time and expense problems with solutions that are the right choice for today and easily adapt to the uncertainties of tomorrow. Time and expense are better together, which is why DATABASICS addresses these two critical business processes with absolute ease in one solution.

Award-winning 24/7 Customer Support

Stevie Awards and Best in Biz Awards year after year

