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What's All the Commotion Over Aggregate Spend?

The Who, What, When, and Where of State Reporting

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Most life sciences companies are aware that state laws impose expense limits and disclosure requirements concerning the marketing and promotion of prescription products. The trouble, however, lies in dealing with the intricacies and ongoing compliance difficulties created by differences among each state's requirements. Moreover, each house of Congress has introduced federal legislation, entitled the Physician Payments Sunshine Act of 2009, and the House of Representatives has introduced its sweeping America's Affordable Health Choices Act of 2009, which includes a Physician Payments Sunshine Provision. These bills, if passed, would impose similar disclosure requirements on a national level. Life sciences companies striving for compliance need to know the who, what, when, and where of state reporting requirements.

Who: Applicability of State Aggregate Spend Laws

Determining whether a company is required to comply with a state's disclosure law depends on the type of product and where it is marketed. For example, Maine, the District of Columbia, and West Virginia require any "manufacturer or labeler of prescription drugs dispensed in [the state or District] that employs, directs, or utilizes marketing representatives in [the state or District]" to disclose marketing expenses.¹ In Maine and DC, the definition of "manufacturer" includes the company's "affiliates."² West Virginia specifically excludes wholesale distributors and retail pharmacists from disclosure requirements.³ On the other hand, Minnesota law expressly includes wholesale distributors.⁴

California imposes requirements on manufacturers, marketers, and labelers of "dangerous drugs," which include both prescription drugs and devices.⁵ As of July 1, 2009, Massachusetts requires both pharmaceutical and medical device manufacturing companies to report aggregate spend data.⁶ Vermont exempts medical device wholesale distributors from its disclosure requirements.⁷ On a federal level, both the Senate and House versions of the Physician Payments Sunshine Act, as well as the House's America's Affordable Health Choices Act of 2009, would require manufacturers of a "covered drug, device, biological, or medical supply" to disclose annual marketing expenses.⁸

What: Understanding the Disclosures Required by Each State

Life sciences companies must identify and track the expenses to be disclosed under each state's law, and provide the necessary level of detail. However, each state has its own threshold for disclosure. Maine and DC require companies to disclose marketing expenses exceeding \$25 per day.⁹ Vermont's newly enacted legislation, effective July 1, 2009, requires manufacturers to report all expenditures and gifts, regardless of value.¹⁰ West Virginia requires companies to report advertising and direct promotion expenses exceeding \$100 in the aggregate to each prescriber.¹¹ Massachusetts requires companies to disclose payments of \$50 or more made to healthcare practitioners ("HCPs")

in relation to the company's sales and marketing.¹² Unlike other states which require companies to report gifts and expenditures exceeding a certain threshold, Minnesota prohibits companies from giving gifts to a HCP valued in excess of \$50 per year.¹³ Minnesota also requires companies to report payments exceeding \$100 associated with medical conferences, honoraria, and consulting services of a practitioner.¹⁴ On a national level, the Senate version of the Physician Payments Sunshine Act would require companies to report annually on a variety of marketing expenses exceeding \$100 in the aggregate.¹⁵ The House of Representatives version of the bill would set the reporting threshold at \$25.¹⁶ The Physician Payments Sunshine Provision of the House's America's Affordable Health Choices Act would set the threshold at just \$5.¹⁷

Some states have even imposed lobbying laws on the activities of life sciences company representatives. For example, Kentucky's Executive Branch Ethics Commission advisory opinion and amendments to Louisiana law expressly state that certain company representative activities constitute "lobbying" and impose limitations and disclosures on interactions with certain state-employed HCPs.¹⁸

State reporting forms further demonstrate the difficulties life sciences companies face with compliance. For example, both Maine and DC regulations require companies to report "[all]

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expenses associated with advertising, marketing, and direct promotion" to residents of Maine or DC, respectively.¹⁹ Maine requires a general reporting of advertising expenses, in which the advertising expense must be associated with a value and nature.²⁰ By contrast, the DC form includes its own worksheet for advertising expenses, which must include for each advertising expense such details as the medium type and medium name, if applicable, the product marketed, and the target audience.²¹

When: Staying on Top of Deadlines

Once a company has tracked its marketing expenses, it must meet each state's specific deadlines for reporting these expenses. Maine, DC, and Massachusetts require disclosure reports for the prior calendar year to be filed by July 1st of each year.²² California's law, requiring companies to declare compliance annually, does not specify a deadline, though many companies file around July 1st. West Virginia's report must be filed by April 1st, and Minnesota disclosures are due on May 1st.²³ Vermont, which follows a fiscal year reporting period, has recently enacted legislation that changes its filing date from November 1st, which remains the deadline for 2009, to October 1st for 2010 and thereafter.²⁴ The Senate version of the Physician Payments Sunshine Act would require companies to report expenses on March 31, 2011, and "on the 90th day of each calendar year beginning thereafter."²⁵ The Physician Payments Sunshine Act and America's Affordable Health Choices Act, both introduced by the House of Representatives, would require disclosures annually on March 31st, beginning in 2012 and 2011, respectively.²⁶ Louisiana's lobbyist disclosure reports are due on the 25th day of each month for the last full month.²⁷

Several states also require companies to file annual compliance certifications or forms identifying the individual responsible for compliance. For example, Vermont requires companies to submit annually a form listing the company's compliance officer and the individual responsible for data collection and reporting.²⁸ The original law required companies to identify annually the individual responsible for compliance by October 1st; the new law requires the Compliance Officer Form to be filed by July 1st.²⁹

Where: The Jurisdictional Limits of State Laws

Another challenge for complying with state reporting requirements is the extent to which the tracked expenses must be reported. Is the requirement personal (i.e., expenses directed towards HCPs licensed in that state), or is it geographical (i.e., all expenditures made within the state regardless where the HCP is

licensed)? Massachusetts released a set of frequently asked questions, providing the following guidance: "As long as the payment is made to a health care practitioner licensed to practice in Massachusetts and authorized to prescribe, it is subject to disclosure."³⁰ Each state's statutes and regulations read differently, and life sciences companies must determine which expenses must be tracked under each state's requirements.

In light of the variations among state disclosure requirements, life sciences manufacturers must make a real effort to comply with current state requirements while also remaining attentive to continuing changes to laws, regulations, and reporting procedures. In this ever-changing reporting landscape, employing a comprehensive electronic tracking system to record spend and monitoring the increasingly complex state (and impending national) disclosure requirements are keys to successful compliance. ■

¹ 10-144-275 ME. CODE R. § 2.03 (2009); D.C. CODE § 48-833.01 (2009); W. VA. CODE § 5A-3C-13 (2009).

² 10-144-275 ME. CODE R. § 2.02-4; D.C. MUN. REGS. tit. 22, § 1800 (2009).

³ W. VA. CODE § 5A-3C-13.

⁴ MINN. STAT. § 151.47 (2009).

⁵ CAL. HEALTH & SAFETY CODE §§ 119402(a)(1-2); 119400(c) (2009).

⁶ 105 MASS. CODE REGS. 970.009 (2009).

⁷ VT. STAT. ANN. tit. 18, §§ 4632 (2009).

⁸ Physician Payments Sunshine Act of 2009, S. 301, 111th Cong. (2009); Physician Payments Sunshine Act of 2009, H.R. 3138, 111th Cong. (2009); America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. (2009).

⁹ D.C. CODE § 48-833.03(a)(3)(b)(1); ME. REV. STAT. ANN. tit. 22, § 2698-A(5) (A) (2009).

¹⁰ VT. STAT. ANN. tit. 18, § 4631a(b)(1).

¹¹ W. VA. CODE R. § 206-1-3 (2009).

¹² 105 MASS. CODE REGS. 970.009(1).

¹³ MINN. STAT. § 151.461.

¹⁴ Id. § 151.47.

¹⁵ Physician Payments Sunshine Act, S. 301.

¹⁶ Physician Payments Sunshine Act, H.R. 3138.

¹⁷ America's Affordable Health Choices Act, H.R. 3200.

¹⁸ Kentucky Executive Branch Ethics Commission, Ad. Op. 06-5 (Apr. 10, 2006); KY. REV. STAT. ANN. § 11A.201 et seq. (2009); LA. REV. STAT. ANN. § 49:71-78 (2009).

¹⁹ 10-144-275 ME. CODE R. § 2.04-1; D.C. MUN. REGS. tit. 22, § 1801.1(a).

²⁰ ME PDMC Record Layout Spreadsheet, available at: http://www.maine.gov/dhhs/boh/documents/clinical_trials/Marketing_Report_Layout050609.xls (last visited July 13, 2009).

²¹ 2008 Prescription Drug Marketing Costs form, available at: http://hrla.doh.dc.gov/hrla/lib/hrla/pharmacy_control/2008_prescription_drugmarketing-costs.xls (last visited July 13, 2009).

²² ME. REV. STAT. ANN. tit. 22, § 2698-A(3); D.C. CODE § 48-833.02; 105 MASS. CODE REG. 970.009.

²³ W. VA. CODE R. § 206-1; Minnesota Statutes §151.461 – Gifts to Practitioners Prohibited, Frequently Asked Questions, available at: <http://www.phcybrd.state.mn.us/forms/giftsfaq.pdf> (last visited July 13, 2009).

²⁴ VT. STAT. ANN. tit. 18, § 4632.

²⁵ Physician Payments Sunshine Act, S. 301.

²⁶ Physician Payments Sunshine Act, H.R. 3138; America's Affordable Health Choices Act, H.R. 3200.

²⁷ LA. REV. STAT. ANN. § 49:76(B).

²⁸ VT. STAT. ANN. tit. 18, § 4632.

²⁹ Id.

³⁰ "Frequently Asked Questions – Pharmaceutical and Medical Device Manufacturer Conduct," Apr. 20 2009, available at: http://www.mass.gov/Eeoehs2/docs/dph/quality/healthcare/pharmaceutical_medical_device_conduct_faq.pdf (last visited July 13, 2009).

What Does "On-Demand" CRM Mean for a Pharmaceutical Company?

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Sam Barclay

The term "on-demand" appears in almost every article published about customer relationship management (CRM) software these days. But what does "on-demand" mean and what are the potential benefits and pitfalls for the pharmaceutical industry? On-demand refers to the ability to obtain software without capital expenditures, dedicated IT resources, annual maintenance agreements and lengthy implementations. It is the ideal solution for some organizations, especially small to medium-sized companies, that prefer to reduce costs by outsourcing the security, hosting, and daily operation related to deploying an enterprise application.

Whether an on-demand delivery model (in contrast to a traditional on-premise approach) is appropriate for an organization requires careful analysis. For instance, some online solutions offer very limited "off-line" functionality. Off-line access means that you have access to the data while not connected to the internet. Check that your solution offers full functionality off-line as well as on-line.

Intense cost pressures are among the leading reasons for the adoption of on-demand, however you should not give up features or functionality if you are choosing an on-demand system. Look for a system that fully supports all pharmaceutical industry requirements and both on-line and off-line access. For instance, a function you should not give up is analytics. Any on-demand system you are looking at should include rich analytics features. You will need these analytics to get the most from the system.

On-demand CRM features a subscription-based operating expense model instead of a capital expenditure model. On-demand pricing is typically expressed on a per employee, per month basis instead of a traditional license agreement fee that is combined with yearly maintenance. With the proliferation of reliable broadband, sales and management have ready access to an on-demand CRM solution. When contrasted with the hardware investment and dedicated IT resources required to support an onsite "behind-the-firewall" enterprise application, the flexibility of an industry-specific, on-demand solution provides a more cost-effective approach.

When deciding whether on-demand or on-premise CRM is right for your company, division, business unit or team, one question trumps all: does your



CRM vendor have the deep industry expertise needed to address your organization's unique business requirements? Ensure that any on-demand application you are considering provides complete industry functionality on-line and off-line, and that major areas such as data analytics are complete.

To make the right decision and fully reap the benefits of on-demand CRM, your CRM vendor needs to have the right blend of software technology and proven business experience.

StayinFront, having over 15 years of experience as a leading pharmaceutical industry CRM provider, recently launched StayinFront EdgeSM, an on-demand solution that addresses the business needs and concerns of the pharmaceutical industry. StayinFront EdgeSM is a rapidly deployed, full-featured and industry-specific on-demand CRM solution. To find out more, please visit stayinfront.com or call Ken Arbadji at 800.422.4520. ■

Navigating Loss Reporting: How to Meet FDA and State Reporting Requirements

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When a manufacturer discovers theft, "significant loss," record falsification or diversion of its product, it has an obligation to report the discovery to the FDA and the appropriate state agency. Failure to do so can result in the imposition of fines and possibly sanctions. Unfortunately, reporting a loss is not as easy as it would seem. Federal regulations do not set specific loss standards, and variations in state regulations further complicate the reporting process.



What Product Loss/Theft/Diversion Must be Reported?

The Prescription Drug Marketing Act of 1987 (PDMA) requires pharmaceutical manufacturers (or their authorized distributors of record) to notify the FDA within 5 working days of becoming aware of a "significant loss" or "known theft" or having reason to believe that diversion/falsification of drug sample records has occurred. These regulations relate exclusively to pharmaceutical products and do not cover the theft or loss of medical devices. However, some states, such as South Carolina¹ and Vermont² impose reporting requirements for lost/stolen medical devices.

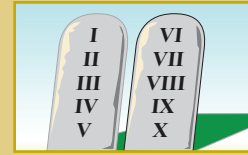
Setting the "Significant Loss" Threshold

PDMA regulations do not define "significant loss" or even provide a percentage threshold above which a loss must be considered "significant." So, each manufacturer needs to self-define the level of loss it considers to be "significant." Manufacturers can take a simple approach and set the significant loss threshold based on the number or percentage of missing samples over a predetermined time period, or they can utilize a methodology that considers various factors, such as:

- a. The dollar amount of the loss
- b. The number of sample units lost
- c. The size of the manufacturer and/or authorized distributor of record
- d. The number of sales representatives engaged in sampling
- e. The size of the total inventory of the drug samples for the manufacturer and/or authorized distributor of record
- f. The value of the total inventory of the drug for the manufacturer and/or authorized distributor of record
- g. The manufacturer's past experiences with sample losses
- h. Whether the drug has a particularly high potential for diversion, including any local trends or other indicators of the drug's diversion potential
- i. The level of accuracy of the manufacturer's internal audit and security system
- j. The circumstances surrounding the loss

Exactly how to calculate the significant loss threshold is left to each manufacturer's discretion. In instances in which a manufacturer is unsure whether a loss is "significant," the manufacturer should proceed as though the loss is significant and notify the FDA accordingly. If the manufacturer later determines that the loss was not significant, the manufacturer can submit a supplemental report to the FDA explaining the situation.

The Ten Commandments of Document Retention, Retrieval and Destruction



1. Thou Shall Establish a Written Retention Policy.
2. Thy Retention Policy Shall Comply with Applicable Regulatory Requirements.
3. Thou Shall Customize Thy Retention Policy to Meet Business Needs.
4. Thy Retention Policy Shall Acknowledge all Forms of Media (e.g., electronic, hard copy, voicemail, photographs, diagrams, drawings, email, web-based, etc).
5. Thou Shall Train Everyone on Thy Retention Policy.
6. Thou Shall Act Reasonably and Consistently in Creating, Following and Enforcing Thy Retention Policy.
7. Thou Shall Not Destroy Documents Before Thy Retention Period has Expired.
8. Sometimes, Thou Shall Protect Documents Even After Thy Retention Period Has Expired (i.e., when litigation or potential regulatory issues exist concerning those documents).
9. Thou Shall Retain Records Documenting the Destruction of Documents.
10. Thou Shall Assure that Documents are Stored in a Safe, Secure Location from Which They are Readily Retrievable.

At the 2008 PDMA Alliance Conference in New Orleans, Rhonda Sobral O'Toole, Esq., StayinFront's Director of Compliance, received the distinction of being selected to give an educational presentation to attendees on document retention, retrieval and destruction. The article above provides a brief overview of the topics discussed during that presentation. If you wish to see the full presentation, please visit www.stayinfront.com.

When Does the Reporting Clock Start Ticking?

PDMA regulations require FDA notification within five (5) working days of a manufacturer (or its authorized distributor of record) "becoming aware" of significant loss or theft or after having "reason to believe" that there is diversion/falsification of drug sample records.³ Manufacturers should note that the level of certainty required to trigger the notification requirement is significantly less strict for record falsification/diversion than for loss/theft – requiring FDA notification for even suspected falsification/diversion.

In contrast to suspected diversion/falsification, the FDA does not require manufacturers to report inventory discrepancies as soon as they are detected. Instead, the FDA expects manufacturers to conduct some type of internal investigation that will allow them to distinguish between accounting mistakes/mathematical errors and actual reportable losses/theft.⁴ These internal investigations could take 30 to 90 days to complete in order to give manufacturers time to: (1) obtain third-party/vendor reports, (2) process data regarding shipments, transfers, & returns that may still be in the distribution pipeline, (3) collect and compare paper and electronic records and (4) analyze and reconcile the collected data. Since manufacturers need this time to determine whether a true loss or theft has occurred, the 5 working days does not typically begin to run until the manufacturer's internal investigation has been completed.⁵

If the inventory discrepancy is the result of an accounting error, inventory mistake or is otherwise explainable, the FDA does not need to be notified. If, however, the inventory discrepancy cannot be resolved and the manufacturer has determined that a reportable event has occurred, the manufacturer must notify the FDA by telephone or in writing within five (5) business days of that determination.⁶

In contrast to the PDMA requirements, the notification window for state authorities varies from state to state. Here is a sampling of states whose notification provisions differ from the PDMA regulations:

Deadline for Notifying State Authority	
State	Time Period
Colorado ⁷	30 calendar days
Ohio ⁸	Immediately upon discovery
Louisiana ⁹	3 business days
Missouri ¹⁰	7 business days
Indiana ¹¹	7 business days
Florida ¹²	3 working days
Washington ¹³	By end of next business day (samples)

Submitting the Report

Within 30 days of notifying the FDA about a significant loss/theft/diversion, the manufacturer (or its authorized distributor of record) is required to submit "a complete written report including the reason for and the results of the investigation conducted by the manufacturer."¹⁴ Once again, each state has its own standards, which may be more or less demanding than the FDA requirements. For example, Ohio, Florida and Indiana all have different requirements:

How and What to Report	
State	Reporting Method
Ohio ¹⁵	By telephone. Report to be made immediately upon the discovery of the theft or significant loss.
Florida ¹⁶	By fax. The report must include: the identity of the licensed establishment, the drug name, name of the manufacturer or distributor, the dosage form, strength, container size, quantity, lot number; brief description of the circumstances surrounding the theft or loss and a contact person's name and telephone number.
Indiana ¹⁷	Must provide copy of police report - if one was created as a result of loss/theft.

Significant loss/theft/diversion reporting requirements are varied and complex. Understanding the nuances of state and federal regulations is the first step to ensuring compliance and avoiding unnecessary fines and penalties. ■

¹ S.C. CODE ANN. § 40-43-89 (2009).
² VT. STAT. ANN. tit. 26, § 2063 (2009).
³ 21 CFR 203.37 (a) & (b).
⁴ FEDERAL REGISTER, Vol. 64, No. 232, 12/3/99, page 67741.
⁵ See FEDERAL REGISTER, Vol. 64, No. 232, 12/3/99, page 67741.
⁶ 21 CFR 203.37 (a)(1) & (b) (1).
⁷ 3 COLO. CODE REGS. § 719-1, 15.05.13 (2009).
⁸ OHIO ADMIN. CODE 4729:9-16 (2006).
⁹ LA. ADMIN. CODE tit. 46 § 303, 313 (2008).
¹⁰ MO. CODE REGS., ANN. tit. 20, § 2220-5.030 (2008).
¹¹ IND. CODE § 25-26-14-17 (2009).
¹² FLA. ADMIN. CODE ANN. r. 64F-12.013 (2007).
¹³ WASH. REV. CODE § 69.45.030 (2009).
¹⁴ 21 CFR 203.37 (a) (3) & (b) (3).
¹⁵ OHIO ADMIN. CODE 4729:9-16 (2006).
¹⁶ FLA. ADMIN. CODE ANN. r. 64F-12.013 (2009).
¹⁷ Indiana Board of Pharmacy

About StayinFront, Inc.

StayinFront, Inc. is a leading global provider of CRM and decision support solutions that improve sales and marketing effectiveness. With a persistent focus on helping companies sell more and manage better, StayinFront products and services are renowned for improving online and offline productivity. Quickly deployed and easy to use, StayinFront CRM helps sales and management teams target, prepare and execute business plans, while also providing the actionable analytics to support data-driven decisions. StayinFront has been chosen globally as a strategic partner by many of the world's top life sciences, consumer goods, financial services and business-to-business companies, and StayinFront solutions have been implemented in over 40 countries in 12 languages.

Headquartered in Fairfield, NJ, StayinFront has offices in Illinois, the United Kingdom, India, Ireland, Australia, Singapore and New Zealand. The Company can be contacted via the web at stayinfront.com. 107 Little Falls Road, Fairfield, NJ 07004
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About Redi-Mail Direct Marketing

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About Porzio, Bromberg & Newman, P.C.

Porzio, Bromberg & Newman, P.C. (Porzio) is committed to serving the legal needs of the life sciences industry. Our services include regulatory compliance audits and counseling, the creation of corporate compliance programs, and the facilitation of internet-based and on-site training for sales and marketing compliance personnel. During the past five years, Porzio has provided more services to the life sciences industry than to any other industry.

Additionally, Porzio's dedication to the life sciences industry is evidenced by its active participation in the HealthCare Institute of New Jersey. This association of research-based pharmaceutical and medical technology companies is dedicated to the development and implementation of sound public health and business policies.

For more information on the variety of services Porzio provides, please visit our website at www.pbnlaw.com or contact us at our Morristown, NJ location. Ph: 973.538.4006
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About Porzio Pharmaceutical Services, LLC

Porzio Pharmaceutical Services, LLC (PPS) is dedicated to helping the life sciences industry comply with the growing body of federal and state regulations that govern marketing and sales practices. PPS provides companies with easily accessible, comprehensive information resources such as Porzio Compliance Digest, Porzio Compliance Modules, Porzio EXP, and ePorzio. For more information, please visit our website at www.porzio-pharma.com or contact our Morristown, NJ office.
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We hope the information provided in this newsletter is helpful. If you have a perspective or opinion on state regulation and compliance you would like to share, or other contributions and comments, please contact:

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