

# Thought Leadership

Sales and Marketing Compliance



**PORZIO**  
BROMBERG & NEWMAN P.C.

Volume 2, Issue 8 Summer 2008

## Can Drug Samples be Given to a "Doc in the Box?"

By Rhonda Sobral O'Toole, Director of Compliance, StayinFront, Inc.



Rhonda Sobral O'Toole

Some retail pharmacies are expanding their businesses to include small medical clinics or medical offices. These so-called "doc in the box" facilities are a convenience to consumers – often being open on weekends and after regular office hours. However, they can create a real headache for pharmaceutical sampling.

By law, pharmaceutical samples cannot be given to retail pharmacies. Only hospital pharmacies and the pharmacy of "another health care entity"<sup>1</sup> can receive samples. A health care entity is defined as "any person that provides diagnostic, medical surgical or dental treatment or chronic or rehabilitative care."<sup>2</sup> Retail pharmacies are expressly excluded from the "health care entity" definition.<sup>3</sup> So, when a physician's office is physically located within a retail pharmacy, will the FDA perceive the sample as being given to the pharmacy or the physician?

Under the PDMA definitions, a person cannot simultaneously be a health care entity and a retail pharmacy.<sup>4</sup> Logically, one would assume that a physician would have to be considered a "health care entity" rather than a retail pharmacy. But what if the physician wears a CVS lab coat, has CVS printed on business cards or medical intake sheets, and conducts his examinations behind a screen in a section of the pharmacy that is not physically separated from the rest of the store? Is he really just an employee of the pharmacy who happens to be a physician? If so, this would mean that giving him samples would be the same as giving them to the retail pharmacy, which is expressly prohibited.

To further complicate matters, the FDA has requirements concerning the way pharmaceutical samples can be stored and handled after being received by a "doc in the box." Since retail pharmacies are prohibited from receiving pharmaceutical samples, any samples given to a physician must be stored in an area within the physician's office or clinic that is separate from the retail pharmacy and, most importantly, not within its control. Samples received by a physician that are stored within the pharmacy itself or within any area the pharmacy controls would likely raise a red flag with the FDA since such samples are at risk for being sold, purchased, traded, or distributed in violation of the PDMA. Moreover, such samples may be perceived by the FDA as having been given to the pharmacy rather than to the physician in violation of federal regulations.



There are various safeguards pharmaceutical manufacturers should consider when dealing with these types of situations. First, sales representatives should be properly trained to realize that a pharmacy "doc in the box" has additional sampling issues not typically associated with other physicians. Second, sales representatives should know how to evaluate and effectively market drugs in such situations before leaving behind any drug samples. Third, CRM software should be tailored to provide special alerts and instructions for sales representatives marketing to a "doc in the box." Finally, before permitting its representatives to leave samples behind, the manufacturer could require written documentation from the physician establishing that the physician and pharmacy are truly separate and distinct entities and that drug samples will be stored in a separate area not within the pharmacy's control. To make this process simple, the desired language could be added to the receipt form the physician is required to sign upon receiving drug samples. These suggestions are not all-inclusive. Each manufacturer's approach to assuring PDMA compliance in this situation may vary.

In short, while samples can be given to licensed physicians practicing within a clinic or office located within a retail pharmacy, such sampling should only be done with great care after the manufacturer has assured itself that such sampling is in full compliance with FDA regulations.

<sup>1</sup> 21 CFR 203.3 (h)(2)(iii)

<sup>2</sup> 21 CFR 203.3(q)

<sup>3</sup> 21 CFR 203.3(q) expressly states that the definition for "health care entity" "does not include any retail pharmacy or any wholesale distributor."

<sup>4</sup> 21 CFR 203.3(q)

## Data Cleansing: Improving the Quality of Your Data

"Garbage in. Garbage out." We have all heard the expression and many of us have had to deal with the consequences. The accuracy of data is critical to making correct business decisions and assuring regulatory compliance. Inaccurate data can be costly and damage a company's reputation.

Assuring the quality of physician data is especially important. Among other things, the FDA requires that pharmaceutical sampling and aggregate spending be accurately recorded and fall within certain limits. If, however, the same physician appears multiple times in the database (as though he/she were several different people), the company places itself at risk for inadvertently over-sampling and/or exceeding aggregate



spending limits for a particular physician. Once a violation has occurred, it is too late.

### Scenario #1

- State X has an annual aggregate spending limit of \$100.00
- From January 2007 through April 2007, ABC Drug Co. Sales Representative #1 spends \$80.00 marketing drugs to Dr. James D. Smith, who has an office located within State X.
- In May 2007, Dr. James D. Smith moves his office to a different town in State X which is outside Sale Representative #1's territory. Dr. Smith also decides he wants to be known by his middle name, David.
- From June 2007 through October 2007, ABC Drug Co. Sales Representative #2 spends \$80.00 marketing drugs to Dr. J. David Smith in State X.
- During its year-end audit ABC Co discovers for the first time that Dr. James D. Smith and Dr. J. David Smith are actually the same person and that (unfortunately) \$160.00 has been spent marketing drugs to this physician during the 2007 calendar year.

**Result:** Violation of aggregate spending limits has occurred.

Inaccurate physician data can also impede the pharmaceutical company's ability to effectively market to physicians. For example, if multiple physicians are recorded in the database as being the same physician, this could have a negative impact on the sales force.

### Scenario #2

- State X has an annual aggregate spending limit of \$100.00.
- From January 2007 through April 2007, ABC Drug Co. Sales Representative #1 spends \$100.00 in

## Inside This Issue

**Can Drug Samples be Given to a "Doc in the Box?"**

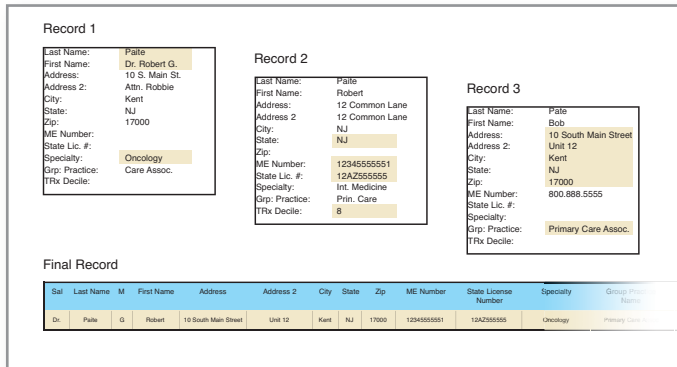
**Data Cleansing: Improving the Quality of Your Data**

**Current Good Manufacturing Practices vs. PDMA Regulations**

**Waiting for the Other Shoe to Drop: Complying with California's Pedigree Law**

marketing drugs to Dr. James D. Smith, II, a cardiologist who has an office located within State X and also works out of the Cardiology Department of General Hospital.

- Dr. James D Smith, III (the son of James D. Smith, II) is also a cardiologist and has an office in a different town in State X but also works out of the Cardiology Department at General Hospital.
  - ABC Co. has recorded Dr. James D. Smith, II and Dr. James Smith, III in their database as being the same physician rather than two separate physicians.
  - In May 2007, when ABC Drug Co. Sales Representative #2 visits Dr. James D. Smith, III and tries to leave behind \$10.00 in marketing materials, he receives a pop-up message on his CRM device advising that this would exceed aggregate spending limits.
- Result:** Sales Representative #2 is discouraged from making further visits to Dr. James D. Smith, III, resulting in potential marketing opportunities being lost.



when one physician has multiple offices or addresses, his/her data will be consolidated and standardized in the system so that the physician will ultimately have only one record in the database. Similarly, name formats should be standardized in the system to help identify and eliminate duplicate records.

Unique physician identifying information, such as Medical Education Numbers (ME), DEA numbers, Board Certification data and group practice information obtained from the American Medical Association (AMA) and other medical associations can be used to verify licensure and identify potentially duplicative physician records to be automatically flagged, de-duped and merged according to the company's specific business rules.

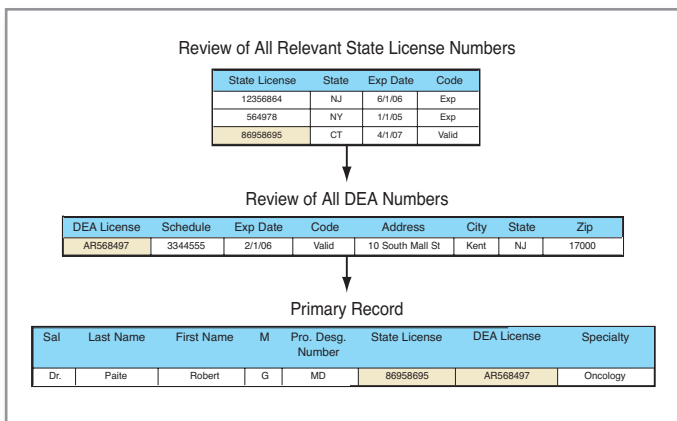
While much of this data cleansing process can, and should be, fully automated, it is important not to lose

While regular company audits may uncover data inaccuracies, this may be too late. Pharmaceutical manufacturers need to transform "garbage" into quality data on a daily basis. Today, there are many tools and processes that can be used to accomplish this task.

Monitoring and maintaining data quality is an ongoing process. Frequent data cleansing is the key to keeping physician doppelgangers<sup>5</sup> out of the system. Using daily or weekly data profiling and data quality tools to analyze data against a set of client-defined quality metrics is one way to assure that the company will have reliable physician data.

Physician data is collected through a number of sources, including daily sales reports, monthly sales reports, physician profiles, wholesale distributor data, and physician accounts. Data from these various sources needs to be correctly integrated and cleansed – with duplicative records being identified and eliminated, or single records being divided among multiple physicians. Ultimately, the overall quality of the data will be enriched and improved in the process.

Physician address data can be validated and standardized using external data sources, such as the National Change of Address (NCOA) or United States Postal Service databases. Missing, incomplete, or incorrect mailing address; and/or email and telephone information can be corrected through this process. For example,



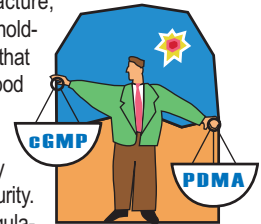
sight of the human factor. Whenever there are discrepancies that can not be easily or definitively addressed by the automated process, human judgment may be necessary to assure that the data cleansing process ultimately results in the creation of the most accurate records. Company business rules will dictate what role human intellect plays in the data cleansing process.



## Current Good Manufacturing Practices vs. PDMA Regulations

When it comes to pharmaceutical sampling, drug manufacturers need to be aware of subtle differences between Current Good Manufacturing Practice (cGMP; 21CFR 210 and 211) and the Prescription Drug Marketing Act (PDMA; 21 CFR 203).

The cGMP regulations protect the public by setting forth the minimum current good manufacturing standards relating to the manufacture, processing, packing, or holding of drugs to assure that such drugs meet the Food Drug and Cosmetic Act standards regarding the products' safety, identity strength, quality, and purity.



Similarly, the PDMA regulations were intended to protect the public against drug diversion by establishing minimum standards relating the sampling and distribution of prescription drugs. While both sets of regulations were intended to protect the public, being in compliance with one regulation does not automatically assure compliance with the other.

Since drug manufacturers who use prescription drug samples to promote sales are subject to both the cGMP and PDMA regulations, here are some noteworthy differences between the two provisions:

<sup>5</sup>A "doppelganger" is the ghostly double of a living person. The literal translation of this German word is "double walker," meaning someone who is acting (e.g., walking) the same way as another person.

Topic	cGMP	PDMA
<b>Drug Distribution Records</b>	Distribution records shall contain the name and strength of the product and a description of the dosage form, name and address of the consignee, date and quantity shipped and lot or control number of the drug product. (21 CFR 211.196)	Distribution records (maintained by either the manufacturer or authorized distributor of record) shall contain lot or control numbers that are sufficient to permit the tracking of the sample units to the licensed practitioner. (21CFR 203.38)
<b>Record Retention</b>	For drugs bearing an expiration date, records shall be retained for at least 1 year after the expiration date of the batch. (21 CFR 211.180 (a))  For certain OTC drugs that are not required to carry an expiration date, records shall be retained for 3 years after the distribution of the batch. (21 CFR 211.180 (a))	Records relating to the distribution of drug samples shall be retained for at least 3 years after the creation of the records. (21 CFR 203.60(d))
<b>Producing Records</b>	Records shall be "readily available" for inspection and copying. Records that can be "immediately retrieved" from another location by computer or other electronic means meet this requirement. (21 CFR 211.180 (c))	Records shall be made available for review and reproduction "within 2 business days" of a request. (21 CFR 203.60 (d))

## Waiting for the Other Shoe to Drop: Complying with California's Pedigree Law

By **John Patrick Oroho, Esq.**, Principal, Porzio, Bromberg & Newman, P.C. and Executive Vice President, Porzio Pharmaceutical Services, LLC.

**Justin C. Hallberg, Esq.**, Associate, Porzio, Bromberg & Newman, P.C. in the firm's Complex Tort Practice Group.



John Patrick Oroho, Esq.

Justin C. Hallberg, Esq.

For some time, pharmaceutical companies have been vigilantly tracking the implementation date of California's pedigree law. Once implemented,

that law will impose the nation's strictest pedigree standards on the pharmaceutical industry and will likely lead to the enactment of equally stringent pedigree laws across the country. This is true, however, only in the absence of any federal pedigree legislation.

California's pedigree law was set to become effective on January 1, 2009, though it contained a provision granting the California State Board of Pharmacy the discretion to delay the implementation date for manufacturers and wholesalers for two years. Taking the pharmaceutical industry by surprise, on March 25, 2008, the California State Board of Pharmacy exercised that discretion and delayed the law's implementation date from January 1, 2009 to January 1, 2011.

Shortly before the Board's decision to delay the implementation of the current pedigree laws, the California legislature proposed two new pedigree bills, S.B. 1270 and S.B. 1307, which would make slight changes to California's existing pedigree law. Interestingly, those proposed bills have been amended several times since March 25, 2008, the day the implementation of the pedigree law was delayed. As such, trying to plan compliance with California's pedigree law is like hitting a moving target.



### The Rationale for the Delayed Implementation Date

The California State Board of Pharmacy determined that the two-year delayed implementation date would serve the best interests of the California public because the additional time was "require[d]" in order to effectively implement electronic technologies to track the distribution of dangerous drugs within the state." This decision surprised the pharmaceutical industry because, in its meeting minutes, the Board appeared to be fully committed to enforcing the January 1, 2009 implementation deadline despite the questions and concerns of many industry members. Indeed, the Board's chairperson asserted at a recent meeting that to protect the California public, the Board did not want to delay implementation. The Board ultimately delayed implementation of the pedigree law, however, because it wanted to provide time to allow the technological aspects required by electronic pedigree to develop and mature, to encourage the industry to engineer a measured scale-up to full compliance with the law, and to give the Board time to work with FDA to develop "federal identifier standards to ensure that California and federal standards remain consistent."

## An Overview of the Current California Pedigree Law

California's pedigree law aims to eliminate counterfeiting by increasing the transparency of the pedigree information and providing a means to immediately verify a drug's authenticity. To that end, the law, in its current form, requires the implementation of electronic track and trace technology and unit serialization. In other words, it requires industry participants, from manufacturers to distributors to pharmacies, to implement technology that electronically reads, verifies and records a product's pedigree information at the lot and individual saleable unit levels. Thus, under California's pedigree law, every saleable unit of a "dangerous drug" must be electronically marked and every transaction in the drug's chain of distribution must be electronically recorded, from its initial manufacture to its final transaction.

### The Details of the Current California Pedigree Law's Requirements

California's current law defines a pedigree as "a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug." Thus, every step of the process that carries the product from the manufacturer to the consumer must be documented and traceable.

Each drug's pedigree must include the following information: source; trade/generic name; quantity; dosage form and strength; date of transaction; sales invoice number; container size; number of containers; expiration date; lot number; detailed information about each owner of the drug, including each person certifying the drug's delivery or receipt; and a certification that the drug's pedigree is true and accurate. If the drug is returned to the manufacturer or wholesaler at any time during its distribution, the drug's pedigree shall include this information as well.

As such, once the pedigree law is implemented, it will be illegal in California to receive or ship a dangerous drug without a pedigree. Non-compliance will subject the offender to a possible citation, fine, order of abatement, and/or suspension or revocation of one's license.

### The Electronic Pedigree Component

To comply with California's current law, pedigree records must be kept electronically in an "interoperable electronic system," which is "an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug." Thus, in effect, product to be distributed in California must contain a unique identification number that can be electronically registered at every stop the product makes during its distribution. Moreover, the electronic system that is employed to comply with this electronic pedigree component must be consistent and ensure compatibility throughout each stage of the distribution process, which requires coordination among all of the industry participants in a product's distribution chain.

## Is Your Marketing Data Redi-Data?



Redi-Data, a Redi-Direct company, provides a host of customized marketing data to meet your company's sales and marketing needs.

**Marketing to Physicians:** Redi-Data supplies hard-to-obtain physician contact information and other data, including:

**Med B2B™:** Detailed, permissioned, CAN-SPAM compliant, workplace email addresses for over 750,000 physicians and medical professionals, along with corresponding postal and demographic data

- Up-to-date, detailed physician data such as: name, present mailing address, medical school, year of graduation, gender, birthplace, birth date, residency training, state licensure, board certification, type of practice, and specialty

- Prescribing practices for physicians, nurse practitioners, physician assistants and certified nurse midwives

**Direct-to-Consumer Marketing:** For businesses advertising directly to consumers, Redi-Data can provide an array of verified consumer data including, demographic, geographic and lifestyle information.

**Business to Business Marketing:** One of the largest databases in the industry with over 12 million businesses.

**Assuring Accurate Mailing Lists:** Mailing lists are only useful when the mail actually reaches its intended recipient. For this reason, Redi-Data provides numerous services to assure accurate address data, including:

**CASS™ Certification:** Verifies address lists through CASS™ certification.

**Deceased Suppression File:** Removes deceased individuals from mailing lists, thereby reducing postage costs and avoiding unnecessary embarrassment.

**National Change of Address (NCOA):** 14% of Americans move each year. Redi-Data uses the NCOA to provide accurate, up-to-date addresses for mailing lists.

**Locatable Address Conversion System**  
Corrects address lists for areas that have undergone permanent address conversions, such as rural routes, highways, box numbers and city-style addresses.

**Delivery Sequence File (DSF):** To ensure that mailing lists conform to U.S. Postal Service addressing standards, Redi-Data uses the DSF file containing valid U.S. Postal Service addresses to verify and update your company's existing mailing lists.

**Delivery Point Validation (DPV):** Removes non-existent addresses from your company's database, thereby dramatically reducing undeliverable mail.

Currently, there are two methods that provide a "standardized nonproprietary data format and architecture" that could be used to comply with California's electronic pedigree requirements: radio frequency identification (commonly known as "RFID") and bar code tagging.

RFID involves affixing electromagnetic chips with encoded, identifying information onto cartons, pallets and individual containers. Operating an RFID system requires purchasing and using the proper electromagnetic chips and equipment to receive and interpret the data encoded in those chips. It is also requires a functioning database that can record and preserve the product's pedigree information in an accessible format. One proven benefit of RFID technology is its ability to track the temperature and light to which a product is subjected. While RFID technology may create more efficient product handling in the long run, it presents significant initial implementation costs. Moreover, RFID is currently unproven and cannot be applied to certain biologics and other sensitive products.

The industry's other option is the use of bar codes. A bar code is a numeric symbol imprinted onto a product's label, which is read by a scanner and electronically recorded. For the past twenty years, bar codes have been used to track merchandise in supermarkets and retail stores around the globe. While the technology required to implement bar code-based electronic pedigree systems could be simply and affordably applied by manufacturers, the implementation and coordination efforts become more expensive and complicated for the downstream product owners because reading a bar code requires a human operator with a scanner and a clear line of sight in close proximity to the bar code.

Unfortunately, neither RFID nor bar codes can be perfectly applied to pharmaceutical products at this time, which was a significant impetus for the Board's decision to delay the law's implementation date.

### **The Unit Serialization Requirement**

Further complicating the industry's compliance efforts, California's current pedigree law also demands unit serialization, which requires that the electronic pedigree record "track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug." As a result, manufacturers must tag each carton, pallet and saleable unit (using either RFID technology and/or bar codes) with a unique and electronically readable identification number. Every time the shipment changes owners, the new owner must electronically record the identification numbers of the shipment and the individual saleable units.

Unit serialization imposes a burden primarily on the manufacturer, which must determine how and where to tag every carton, pallet and saleable unit that it intends to distribute in California. Moreover, once the manufacturer has implemented electronic unit serialization, the remaining industry participants must coordinate their technology so that it is compatible with that used by the manufacturer. It is important to note that unit serialization may require the re-working of product labels, which could have legal ramifications.

## **The Proposed Changes**

Neither of the recently introduced pedigree bills proposes any modification of these electronic pedigree and unit serialization requirements. Rather, they suggest only minor changes and do not affect the current pedigree standards in any meaningful way.

California Senate Bill No. 1270 was introduced February 19, 2008. It has been amended four times since the Board delayed the current pedigree law's implementation date. In its current state, the bill proposes that the Board establish an Electronic Pedigree Task Force, with a specifically defined membership and role in overseeing the industry's efforts to comply with California's pedigree laws.

California Senate Bill No. 1307 was introduced on February 20, 2008, and has been amended twice since the Board delayed the implementation of California's current pedigree law. As it is now written, this bill would require the Board to compel the industry to use federal standardized numerical identifiers on each product and any other standardized data elements of a pedigree record – if such federal standards are developed. In other words, if a federal system is created to identify a product as it moves throughout the nation, California's electronic pedigree requirements must utilize the federal system's identifiers.

## **Conclusion**

While the pharmaceutical industry is currently waiting for the other shoe – namely the passage of federal pedigree legislation – to drop, industry members can be certain that the federal government as well as state governments are very serious about implementing strict pedigree laws. California's current pedigree law established the nation's highest pedigree standards, requiring the industry to move toward compliance with electronic pedigree and unit serialization requirements. Even if California's pedigree law is changed or preempted, it is very likely that a similarly stringent pedigree law will be approved at the state and/or federal level. Therefore, while the pharmaceutical industry waits, it would be wise to keep moving toward compliance with the standards established by California's pedigree law.

<sup>1</sup>John Patrick Oroho, Esq. is a principal of Porzio, Bromberg & Newman, P.C. in the firm's Pharmaceutical Marketing and Sales Compliance and Litigation Department. He is also the Executive Vice President of Porzio Pharmaceutical Services, LLC.

<sup>2</sup>Justin C. Hallberg, Esq. is an associate of Porzio, Bromberg & Newman, P.C. in the firm's Complex Tort Practice Group.

<sup>3</sup>On April 17, 2008, U.S. Representative Steve Buyer sponsored H.R. 5839, a federal pedigree bill. As currently written, it proposes to preempt all state pedigree laws. If this occurs, then compliance with federal law will be the priority for the pharmaceutical industry. However, as this article discusses, it is likely that the federal pedigree law will employ similarly stringent standards to those imposed by the California pedigree law.

<sup>4</sup>CAL. BUS. & PROF. CODE § 4163.5 (2007).

<sup>5</sup>California legislative information, including daily updates on proposed bills, can be found online at <http://www.leginfo.ca.gov/>.

<sup>6</sup>Decision of the California State Board of Pharmacy Pursuant to Business & Professions Code § 4163.5, March 25, 2008.

<sup>7</sup>The California State Board of Pharmacy's Work Group on E-Pedigree meeting minutes are available at <http://www.pharmacy.ca.gov/about/meetings.shtml>.

<sup>8</sup>California State Board of Pharmacy Work Group on E-Pedigree Meeting, 10 (Sept. 20, 2007).

<sup>9</sup>Decision of the California State Board of Pharmacy Pursuant to Business & Professions Code § 4163.5, March 25, 2008.

<sup>10</sup>"Dangerous drugs" are defined under CAL. BUS. & PROF. CODE § 4022 (2007) as those drugs or devices (for humans and animals) that require a prescription or a license to use.

<sup>11</sup>Id. at § 4034(a).

<sup>12</sup>Id. at § 4034(b).

<sup>13</sup>Id. at § 4034(e).

<sup>14</sup>Id. at § 4000 et seq.

<sup>15</sup>Id. at § 4034(a), (f).

<sup>16</sup>California State Board of Pharmacy Work Group on E-Pedigree Meeting, 5 (Sept. 20, 2007).

<sup>17</sup>Id. at 11.

<sup>18</sup>CAL. BUS. & PROF. CODE § 4304(d).

### **About StayinFront, Inc.**

StayinFront, Inc. is a leading global provider of enterprise-wide customer relationship management (CRM) applications, decision support tools, data services and eBusiness systems. StayinFront offers rapidly configured and implemented solutions to manage and integrate all points of customer interaction including sales, marketing, customer support applications and the web. StayinFront has been chosen globally as a strategic CRM partner for more than seventy pharmaceutical companies and StayinFront solutions have been implemented in over twenty countries in twelve 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](http://stayinfront.com). 107 Little Falls Road, Fairfield, NJ 07004 Ph: 973.461.4800 Fax: 973.461.4801

### **About Redi-Mail Direct Marketing**

Redi-Mail Direct Marketing is a results-driven marketing solutions company providing direct marketing services including: consumer, business and healthcare lists, multi-channel marketing, direct mail, email deployment, digital printing, web site development and hosting, database management, data processing, literature, premium and pharmaceutical sample fulfillment.

Redi-Mail Direct Marketing is a member of the Redi-Direct family of companies. Headquartered in Fairfield, NJ, Redi-Mail occupies over 170,000 square feet of secure, state of the art data management and production facilities. The Redi-Mail facilities include an in-house post office and Redi-Mail is an active member of the U.S. Postal Customer Council. The Company can be contacted via the web at [redimail.com](http://redimail.com). 5 Audrey Place, Fairfield, NJ 07004-3401 Ph: 973.808.4500 Fax: 973.808.5511

### **About Porzio, Bromberg & Newman, P.C.**

Porzio, Bromberg & Newman, P.C. (Porzio) is committed to serving the legal needs of the pharmaceutical industry. Our services have included 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 pharmaceutical industry than to any other industry.

Additionally, Porzio's dedication to the pharmaceutical 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](http://www.pbnlaw.com) or contact us at our Morristown, NJ location. Ph: 973-538-4006 Fax: 973-538-5146.

### **About Porzio Pharmaceutical Services, LLC**

Porzio Pharmaceutical Services, LLC (PPS) is dedicated to helping the pharmaceutical industry remain compliant with the growing body of federal and state regulations that govern pharmaceutical marketing and sales. PPS provides companies with easily accessible, comprehensive information resources such as Porzio Pharmaceutical Digest, Porzio Compliance Modules, Porzio EXP, and ePorzio. For more information on PPS products and services, please visit our website at [www.porzio-pharma.com](http://www.porzio-pharma.com) or contact us at our Morristown, NJ location. Ph: 973-538-1690 Fax: 973-538-5146.

*Additional copies of this publication can be requested through any of the contact information listed above.*

*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:*

*Sam Barclay at [sbarclay@stayinfront.com](mailto:sbarclay@stayinfront.com) or  
John Oroho at [jporoho@pbnlaw.com](mailto:jporoho@pbnlaw.com)*