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Marketing Cost Disclosures and Prohibitions - The New Frontier

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Introduction



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The 2007 state legislative sessions have begun with the introduction of bills in at least fifteen states that would require pharmaceutical manu-

facturers to disclose marketing costs incurred in connection with detailing healthcare practitioners. Four states – Maine, Minnesota, Vermont, West Virginia – and the District of Columbia already have laws requiring disclosure with respect to gifts.

A few of the proposed bills would go further than requiring pharmaceutical manufacturers to publicly report how much they and their sales representatives give to doctors each year. A bill being considered in Massachusetts would actually criminalize the giving of gifts (regardless of value) from pharmaceutical representatives to healthcare practitioners.

Academic and medical institutions are also weighing in on this debate with the introduction of gift restriction policies.

Pending State Disclosure Legislation

A plethora of legislation has recently been introduced that would require pharmaceutical manufacturers to disclose the costs associated with marketing to healthcare practitioners. Among the states that have introduced such legislation are Arizona, Connecticut, Hawaii, Nebraska, Nevada, New Hampshire, New Jersey, Rhode Island, and Texas.

For example, the Nebraska legislature has introduced a bill that would require pharmaceutical manufacturers to annually disclose the “value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit” provided by a pharmaceutical manufacturer or representative to any healthcare professional authorized to prescribe in the state.¹

Like many other similar bills, the following would be exempt from disclosure:

- Free samples of prescription drugs intended to be distributed to patients;
- The payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials;
- Any gift, fee, payment, subsidy, or other economic benefit the value of which is less than twenty-five dollars;
- Scholarship or other support for medical students, residents, and fellows;
- Unrestricted grants for continuing medical education programs; and
- Prescription drug rebates and discounts.²

Manufacturers who violate the bill's provisions would be subject to a civil penalty of not more than \$10,000 per violation.³

If this bill is passed, it will join Maine, Minnesota, Vermont, West Virginia, and the District of Columbia as one of the few states that currently have laws that require the disclosure of gifts to physicians.

Pending State Prohibition Legislation

Several states have also introduced bills that would impose a flat prohibition on the provision of gifts to healthcare practitioners.



For example, Massachusetts has a bill pending that would make it unlawful for any pharmaceutical representative to offer or give a “physician or a member of a physician's immediate family or a physician's employee or agent or a healthcare facility or employee or agent of a healthcare facility” a gift of any value.⁴ Practitioners would also be forbidden from accepting any gifts of value from a pharmaceutical representative.⁵ Violators of this proposed law would be subject to fines of up to \$5000 and/or imprisonment up to two years.⁶

Similarly, Wisconsin has introduced a bill that would prohibit manufacturers or distributors of prescription drugs from providing or offering gifts to physicians who are authorized to prescribe and administer drugs in the state.⁷

This bill would exempt only the following two items from disclosure: (1) gifts given or offers made by a manufacturer or distributor to a practitioner who is a relative of the manufacturer or distributor; and (2) product samples given by a manufacturer or distributor to a practitioner for delivery to a patient.⁸

Manufacturers who fail to comply with the bill's restrictions would be subject to a fine of not more than \$10,000 for each violation.⁹

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4 See Massachusetts Senate Docket 1770 (2007).
5 Id.
6 Id.
7 See Wisconsin Assembly Bill 12 (2007).
8 Id.
9 Id.

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1 See Nebraska Senate Bill 674 (2007).
2 Id.
3 Id.

If these bills are passed, Massachusetts and Wisconsin will become the only states with outright bans on essentially all gifts, regardless of value. Minnesota currently prohibits pharmaceutical representatives from offering gifts to physicians that exceed \$50 in a calendar year.

Health System Bans

The debate over whether pharmaceutical representatives should be allowed to market to healthcare practitioners has spilled over from the state legislatures to the health system community. A number of healthcare institutions, including, Stanford University Medical Center, University of California-Davis, University of Michigan, the Hospital of the University of Pennsylvania, and Yale School of Medicine, have proposed or implemented policies to restrict pharmaceutical representative interactions with physicians. According to these institutions, such policies are necessary to reduce the potential for conflicts of interest associated with the prescribing of prescription drugs.

For example, in 2006, the Hospital of the University of Pennsylvania enacted a policy that substantially increased the restrictions on interactions between representatives of pharmaceutical companies and medical, nursing, pharmacy, and other healthcare workers.¹⁰ In addition to setting strict conditions for in-person visits and other contacts, these changes included a ban on gifts, "leave-behinds" (e.g., coffee mugs and pens) and food and drink.

According to the U-Penn policy, pharmaceutical company representatives are required to have a scheduled appointment whenever they visit the Hospital. Vendors who violate these restrictions may have their business privileges revoked.

As more states introduce legislation, the healthcare community will likely continue to implement policies to restrict pharmaceutical marketing as a "self-policing" measure.

Conclusion

Although only a number of states have adopted gift disclosure or prohibition laws, it appears that more and more states may follow this trend. Further, companies must be aware of the impact such legislation is having in the medical community, for example, in major medical and academic institutions. Prestigious public and private universities' bans and prohibitions on interactions with healthcare practitioners, coupled with the proposed Massachusetts and Wisconsin legislation, are clear indicators of the direction of this debate. Consequently, as the legislative session unfolds in 2007, compliance personnel must be vigilant in monitoring bills that would impose more stringent requirements on companies and their sales forces.

The Importance of User Requirements

By Sam Barclay, Vice President of Business Development, StayinFront, Inc.



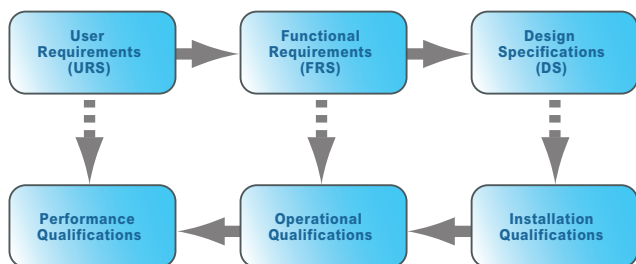
Sam Barclay

The GAMP 4¹ guide to validation is the most widely used, internationally accepted guide for validation of computer systems. It describes a methodology for implementing and validating computer systems

for use in the pharmaceutical industry. At the highest level, the methodology requires that three levels of requirements documentation are matched up with three levels of test protocols, thereby ensuring that the business, functional and technical requirements have been met.

The part of this process that is most commonly executed poorly or not completed at all is the creation of a good User Requirements Specification (URS). Because the URS will be used as the starting point for the detailed and technical designs, it is critical that the URS is detailed, clear and understandable to both the users and the software designers who will build the system, it is the key communication between the users of the software and the builders of the software. The URS is the foundation of a good software project.

Firstly, a good URS is designed to lay out the business requirements in a way that is accessible to the users of the system so that they can validate that their requirements will be satisfied by the proposed system. Secondly, a good URS is key to the creation of the next step in the process – a Functional Requirements Specification



(FRS), and finally the URS is the document against which the software must be finally benchmarked to ensure that the original intention of the business was satisfied.

The key attribute of a URS is that it describes WHAT the software will do, not HOW the software will do it. For example, a URS should describe that the call signature form must allow a medical professional to sign for a sample, but must not allow the medical practitioner to see or access any other information while the computer is in his or her possession. A URS should not specify that this will be achieved by way of a modal dialog that will cover the entire screen area, and which may only be closed using an invisible button. That HOW information is the responsibility of the Functional

The Do's and Don'ts of a Good URS System

DO INCLUDE THE FOLLOWING INTO YOUR URS DOCUMENT:

- DESCRIBE WHAT THE SOFTWARE WILL DO
- USE A MIXTURE OF USE CASES AND DIAGRAMS TO CONVEY HOW THE SOFTWARE WILL BE USED IN PRACTICE
- NUMBER EACH REQUIREMENT LISTED ON AN INDIVIDUAL BASIS FOR REQUIREMENTS TRACEABILITY
- LIST CONSTRAINTS

DON'T INCLUDE THE FOLLOWING INTO YOUR URS DOCUMENT:

- HOW THE SOFTWARE WILL ACCOMPLISH THE WHAT REQUIREMENT
- SCREEN OR REPORT LAYOUTS
- TECHNICAL REQUIREMENTS
- DATA TYPE REQUIREMENTS

¹⁰ For more information about the U-Penn policy, please visit the University's website at: <http://www.med.upenn.edu/1101635>

¹ The Good Automated Manufacturing Guide for Validation of Automated Systems in Pharmaceutical Manufacture version 4 published by ISPE - ISBN: 1-931879-17-6

Requirements Specification, which is the next stage in the development of the requirements.

The first component of the URS is defining what it will do, and who it will do it for. The easiest way to define the 'what' a software application will do is to define WHO will use it and WHAT they will receive out of the system. For instance, defining that a CRM solution will be used by district managers, and that they require to see all the call activity that has been entered into the system by their direct reports for a specific date, and that the output must be viewable and printable is a solid, if high level, User Requirement. Obviously, more detailed User Requirements are needed if the resulting software is to be of any value to the user, but this initial high level requirement does not fall into the trap of defining how the requirement will be met.

The second component of a detailed URS is a list of Constraints. A Constraint is a requirement of the software that must be met, but which is not necessarily directly attributed to a user or an output. A good example of a Constraint in the types of systems that we come across is "The software must operate in accordance with 21 CFR Part 11". This constraint will lead to a number of Functional Requirements (for instance an audit history), and Project Requirements (that the software will be validated). Another example of a Constraint is 'the users are currently equipped with hardware running the XP operating system, and therefore the software must operate on the XP operating platform.

Thirdly, a URS may contain a mixture of Use Cases and diagrams that will convey to the designers and builders of the application how the software will be used in practice. A Use Case is a description of a business process that will be executed through the software, and the inputs and outputs that will be required of the software to fulfill the desired purpose. Diagrams that may assist conveying the use of the software in the business context may include workflow diagrams and dataflow diagrams that show the progression of information in and out of the software.

A good URS does not include any of the following: screen or report layouts; descriptions of interface actions (such as 'saves the record by clicking on the save button' – this is 'how' not 'what' and should be addressed in the FRS); technical requirements (such as a definition of the communication method to be used between the client and server computers); or data type requirements (for instance the URS may state that a medical professional must be designated as a target, but should not state that a checkbox will indicate that the medical professional is a target).

Finally, each requirement listed in the URS should

be numbered on an individual basis, so that future documentation such as the FRS, DS and test scripts can reference each specific user requirement that is addressed. Each user requirement can be traced from the URS through the FRS and via test scripts to prove that each requirement was met.

By creating a detailed and unambiguous URS, the project team can ensure that the project begins with the strongest possible foundation.

Effective Training Allows Users to Get the Most from Their CRM Solution

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

Customer relationship management (CRM) systems, which are designed to manage and integrate data relating to all aspects of customer interaction, are an invaluable resource to pharmaceutical manufacturers. The value that a CRM system brings to a company, however, can depend largely on how well system users have been trained. Effective training is key to understanding the essentials of the system, such as navigation, features, functionality, company policies, procedures and adherence to FDA and other regulatory requirements.



Learning a new software application or managing changes within an existing system can be challenging, even when training occurs in the more traditional face-to-face classroom setting. While one of the key advantages provided by classroom training is the ability for users to ask direct questions and receive personal assistance from trainers and facilitators, Web-based training is gaining popularity and support as an effective complement or alternative to face-to-face training.

Classroom Training Versus Web-Based Training

Two basic types of training generally are available: classroom training and Web-based training – both of which can be tailored to a company's specific needs and supplied by the CRM provider.

Classroom (i.e., face-to-face) training is the most

Sample Data & Off-Label Promotion

Can prosecutors use data from sample distribution as evidence of off-label promotion?

In an era of increased scrutiny and large settlements, zealous prosecutors will undoubtedly use novel methods to pursue pharmaceutical manufacturers. One area that has received significant attention is off-label promotion. According to the Food, Drug and Cosmetic Act, if a pharmaceutical manufacturer promotes its product for uses other than those included in the FDA-approved label, that manufacturer has engaged in off-label promotion, which "misbrands" prescription drugs and is expressly prohibited.¹ Proving off-label promotion, however, is difficult, especially when it occurs during a detailing session between a sales representative and a physician. But industrious prosecutors may already have all the information they need to establish off-label promotion.

Pharmaceutical manufacturers amass a large amount of data in their sample accountability programs. The Prescription Drug Marketing Act ("PDMA"), a federal law, for example, requires manufacturers to maintain a myriad of written records and reports, including written requests by physicians for samples.² The manufacturer also must retain records of lot numbers that can be traced to individual physicians.³ This data is fertile ground for prosecutors to harvest important off-label promotion evidence.

PDMA requirements establish a paper trail that may provide evidence of off-label promotion. Sample distribution records and sales representatives' call plans provide ample information to determine a physician's specialty, which is significant because sampling physicians that do not practice in the field that the product has an approved indication is suspect. Also, distribution of samples immediately after a physician asks an unsolicited off-label question of a manufacturer's medical science liaison or medical department may also trigger suspicions.

The best solution for manufacturers is to monitor sample distribution data to catch evidence of off-label promotion before a prosecutor does. Establishing policies and procedures that include measures to identify abnormal sample distribution activities allows a pharmaceutical manufacturer to detect and correct instances of off-label promotion.

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¹ 21 USC 352.
² 21 CFR 203.30(b)(1)(i)-(vi).
³ 21 CFR 203.38 (b).

traditional method of training. Knowledgeable trainers, who can tailor their answers to meet the needs of the user group, are able to address questions as they arise in this type of setting. This approach quickly eliminates confusion because the instruction can be easily re-directed to focus on the most misunderstood topics among the participants.

Web-based training (as its name suggests) occurs over the Internet. While Web-based training does not involve the same level of personalized attention available in the classroom setting, several key features make it an appealing alternative. For example, Web-based training allows users to learn at their own pace. They can repeat the training course as many times as necessary to master the material, without feeling nervous or pressured. Web-based training also provides the company with key training metrics. Assessments, presented at the end of each web-based course, test the user's comprehension level. Reports, which are easily generated, create an audit trail that can be shown to regulatory agencies, if needed, to substantiate that all company employees have been trained properly on rules and regulations.

A key advantage of Web-based training is the ability to create curriculum content that is specifically tailored to meet each organization's training needs. Web-based training offers an innovative, practical and sustainable solution to introduce new topics, applications or enhanced system functionalities to a sales force on a convenient and cost-effective platform, while enabling the tracking of key information. Users are able to receive training at a pace and time that is convenient for them and the organization is ensured that system users receive extensive training in the most cost-effective manner.

Training Employees About Policies, Procedures and Regulatory Affairs:

The FDA regulates numerous aspects of the prescription drug industry. Since violations of FDA regulations can result in significant fines and penalties, regulatory compliance is a key concern for all pharmaceutical manufacturers.

Proper training is one way to assure compliance. For example, Part 203.34 of the Prescription Drug Marketing Act of 1987 ("PDMA") requires pharmaceutical manufacturers who distribute drug samples to physicians through their sales representatives to "establish, maintain and adhere to written policies and procedures describing its administrative systems" relating to this drug distribution.¹

In order for sales representatives to be able to "adhere" to the manufacturer's Standard and Detailed Operating Procedures ("SOPs/DOPs"), they must fully understand them. Proper training ensures that they receive the knowledge to remain compliant.

Ideally, initial SOP/DOP training would occur in a classroom setting so that sales representatives could ask questions and explore all the nuances of the organization's relevant SOPs/DOPs. Thereafter, Web-based training (which is easily updated and quickly disseminated) would be the best choice to inform them about SOP/DOP revisions. Also, reports of Web-based training test results create an audit trail that can be produced for the FDA (should the need arise) to establish that proper employee training has occurred.

Choosing the Best Training Approach

Pharmaceutical sales representatives often require training in various areas such as customer relationship management (CRM) software, product offerings, FDA regulations and marketing initiatives to name a few. These topics which vary by nature, require different training approaches or programs.

New product launches, pre-training classes and refresher courses provide other examples of situations in which training is a key component of essential information dissemination.

When it comes to training employees under any of these circumstances, the optimal solution is to use a combination of training techniques. While initial classroom training, followed by specialized Web-based training is the best approach, Web-based training is proving to be a successful and measurable method for learning a wide variety of topics and skills. Both the pharmaceutical manufacturer and the CRM provider need to work together to develop a customized training program that will meet the company's needs.

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, Ireland, Belgium, Australia, Singapore and New Zealand. The Company can be contacted via the web at stayinfront.com. 107 Little Falls Road, Fairfield, NJ 07004 Ph: 973.461.4800 Fax: 973.461.4801

About Redi-Mail Direct Marketing, Inc.

As a leading industry provider of marketing support services, Redi-Mail Direct Marketing combines world-class technology with custom web application development and hosting, database management, lettershop and fulfillment capabilities to deliver true turnkey solutions to direct marketing and fulfillment requirements. As a licensee of the American Medical Association (AMA) Physician Masterfile database, Redi-Mail offers online physician counts and targeted direct mail lists on over 800,000 US based physicians through Redi-Med Data™ our interactive medical database system.

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. 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 needs of the pharmaceutical industry, from regulatory compliance counseling to governmental affairs, from litigation to real estate and corporate. During the past five years, Porzio has provided more services to the pharmaceutical industry than to any other industry.

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

To find out more about the various services that Porzio provides, please visit our website at 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 governing pharmaceutical marketing and sales. PPS provides companies with easily accessible, highly efficient information resources, such as Porzio Pharmaceutical Digest, Porzio Compliance Modules and ePorzio.

To find out more about the various services that PPS provides, please visit our website at www.porzio-pharma.com or contact us at our Morristown, NJ location. Ph: 973-538-1690 Fax: 973-538-5146.

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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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¹ See 21 C.F.R. 203 (b)